CEMP-RT Engineer Manual 200-1-4	Department of the Army U.S. Army Corps of Engineers Washington, DC 20314-1000	EM 200-1-4 30 June 1996
	Environmental Quality Risk Assessment Handbook Volume II: Environmental Evaluation	
	Distribution Restriction Statement Approved for public release; distribution is unlimited.	

DEPARTMENT OF THE ARMY
U.S. Army Corps of Engineers
Washington, DC 20314-1000

EM 200-1-4

CEMP-RT

Manual
No. 200-1-4

30 June 1996

Environmental Quality
RISK ASSESSMENT HANDBOOK,
VOLUME II: ENVIRONMENTAL EVALUATION

1. Purpose. The overall objective of this manual is to provide U.S. Army Corps of Engineers (USACE) Hazardous, Toxic, and Radioactive Waste (HTRW) managers and technical proponents with the recommended basic/minimum requirements for planning, evaluating, and conducting ecological risk assessments, consistent with USACE principles of good science and in defining expected quality and goals of the overall program.

2. Applicability. This manual applies to ecological risk assessment aspects for all USACE HTRW investigations, studies, and designs under the Department of Defense, Defense Environmental Restoration Program (DERP), Base Realignment and Closure (BRAC), U.S. Environmental Protection Agency (EPA) Superfund Program, Civil Works, and Work for Others. EM 200-1-4, Risk Assessment Handbook, Volume I: Human Health Evaluation, provides guidance on human health risk assessments performed for all HTRW projects.

3. General. Chapter 1 of this manual presents the purpose, scope, concept, and policy considerations, and the use of risk assessment in HTRW programs. It provides a description of the USACE HTRW program, the quality required for performance of ecological risk assessment, and an understanding of how risk assessments serve management decision needs. Relevant Federal statutes/regulations, agency guidance and directives and state requirements are also highlighted in this chapter. Chapter 2 presents the major scoping and project planning elements under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and the Resource Conservation and Recovery Act (RCRA) as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Particular emphasis is placed on the early development of an Ecological Conceptual Site Model (ECSM). utilizing the data quality objectives planning process presented in EM 200-1-2, Technical Project Planning Guidance for HTRW Data Quality Design, to identify data needs and optimize data collection efforts. Chapters 3 through 8 are intended to provide the risk assessor with the minimum content expected to be included in an ecological risk assessment to adequately serve site decision requirements. They summarize the key components of a Screening Ecological Risk Assessment (Chapter 3), the four tiers employed for Baseline Ecological Risk Assessments (Chapters 4, 5, 6, and 7), and Ecological Risk Assessment of Remedial Alternatives (Chapter 8). These chapters stress the importance of properly identifying the receptors and chemicals of concern and a thorough understanding of the dynamics of interrelationships of multiple receptors and pathways in the development/refinement of an ECSM before embarking on estimating exposure point concentrations. They also highlight the need for characterizing site hazard or risk objectively and realistically to satisfy the regulatory requirement of protection of the environment. Chapter 9 concerns presentation of the risk assessment results for use in risk management and decision-making, focusing on the decisions and criteria needed for making those decisions. Both risk and nonrisk factors are presented for consideration by the manager. This chapter

emphasizes the need for balancing protection of the environment with other project constraints based on the level of confidence and uncertainty in the risk assessment results. Risk results are used for evaluating the need for a removal action, interim corrective measures, or remediation, and to provide the decision criteria and rationale for the selection of remedial alternatives, if required for site closeout. The chapter concludes that the HTRW project team has the responsibility to present risk information as management options to the customer, documenting the uncertainty and rationale.

FOR THE COMMANDER:

ROBERT H. GRIFFIN
Colonel, Corps of Engineers
Chief of Staff

NOTICE

BACKGROUND: The Hazardous, Toxic, and Radioactive Waste (HTRW) risk assessments are performed by USACE on behalf of Federal entities/agencies, pursuant to CERCLA/RCRA. under the Defense Environmental Restoration Program (DERP). Base Realignment and Closure (BRAC), and Work for Others Programs. The overall objective of this handbook is to provide USACE HTRW managers and technical proponents with the recommended basic/minimum requirements for planning, evaluating, and conducting risk assessments, consistent with USACE principles of "good science" and in defining expected quality and goals of the overall Program. The resulting risk assessment should be scientifically sound, defensible, and site-specific for use by site managers or agencies in making site decisions.

STATUTES: CERCLA, Section 120 (Federal Facilities) and Section 121 (Response Actions); RCRA Section 3004(u)(Technical Requirements for Corrective Action), 3OO5(c)(Permitting and Omnibus provision), 3008 (h)(Corrective Action Orders), and Section 6001 (Federal Facilities).

REGULATIONS: 40 CFR 300.430 (d), 40 CFR 300.430 (e), 40 CFR 264 Subpart S, and 40 CFR 270.32(b)(2)

AUTHORITY: Executive Order 12580, CERCLA Sections 104 and 115 delegate President's authority for response action to the lead agency (DoD and other Federal agencies) which are also the Natural Resource Trustees having jurisdiction, custody, and control over their lands. Within the definition of a Natural Resource Trustee, DoD is authorized under CERCLA Section 211 to be the lead agency for CERCLA or the National Priority List (NPL) sites at current or former DoD facilities and to implement the Defense Environmental Restoration Program.

POINTS OF CONTACT:

Dr. Reuben Sawdaye
Directorate of Military Programs
Environmental Restoration Division
HQUSACE (CEMP-RT)
20 Massachusetts Avenue, NW
Washington, DC 20314-1000

TELEPHONE: (202) 761-8881

Terry L. Walker
HTRW Center of Expertise (CX)
USACE (CEMRO-HX-H)
12565 West Center Road
Omaha, Nebraska 68144-3869

TELEPHONE: (402) 697-2591

FUTURE REVISIONS: This handbook will be reviewed on an annual basis for revisions, and updates issued accordingly.

DEPARTMENT OF THE ARMY
U.S. Army Corps of Engineers
Washington, DC 20314-1000

EM 200-1-4

CEMP-RT

Manual
No. 200-1 -4

30 June 1996

Environmental Quality
RISK ASSESSMENT HANDBOOK,
VOLUME II: ENVIRONMENTAL EVALUATION

Table of Contents

List of Tables

List of Figures

List of Case Studies

List of Exhibits

Chapter 1
Introduction

1.1 Purpose and Scope

This manual, ***Risk Assessment Handbook: Volume II - Environmental Evaluation,*** provides technical guidance to the U.S. Army Corps of Engineers (USACE) risk assessors and risk assessment support personnel for planning, evaluating, and conducting ecological risk assessments (ERAs) in a phased Hazardous, Toxic, and Radioactive Waste (HTRW) response action. The manual, a compendium to the ***Risk Assessment Handbook: Volume I - Human Health Evaluation*** (EM 200-1-4, USACE 1995a), encourages the use of "good science*' within the framework of existing U.S. Environmental Protection Agency (EPA) ERA guidelines. The purpose of this manual is to provide USACE HTRW program managers and technical proponents with recommended basic/minimum requirements for planning, evaluating, and conducting ERAs and to define the expected quality and goals of the overall program.

Risk characterization is a similar process for both human health and ecological risk assessments. The fundamental paradigm for human health risk characterization has four phases: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. Similarly, the fundamental framework for ecological risk characterization includes four analogous phases: (1) problem formulation, (2) ecological effects characterization, (3) exposure characterization, and (4) risk characterization.

This manual encourages the concurrent assessment of human and ecological risks so that data collection activities are coordinated and risk managers are provided risk characterization results in a timely manner. Risk characterization results for human and ecological receptors should be reasonable and communicated to the risk managers in a clear and unbiased manner to facilitate the making of balanced and informed risk management decisions.

1.1.1 Objectives

The overall objective of this manual is to allow the users to be familiar with the ERA process so that quality data will be collected and used in preparing a site-specific ERA. Specifically, the objectives are:

- To provide guidance for all ERAs completed under contract with USACE or those which USACE provides technical oversight (including active and formerly used defense sites [FUDS] and other Federal agencies/facility sites), in compliance with Federal environmental laws and regulations.
- To allow users to be familiar with the application of the data quality design process with respect to conducting ERAs, so that data collected will support ERA conclusions.
- To highlight those decision criteria specific to each phase of project execution that support risk management decision-making within the framework of USACE's HTRW programmatic approach.
- To provide minimum requirements for evaluating contractor-prepared ERAs, ensuring that the assessment will adequately support site decisions of an HTRW response action.
- To acknowledge areas of uncertainties where "good science," based on professional judgment and sound scientific principles, is used to determine the need for removal actions or interim measures, further investigation, further action, or no further action needed (site closeout).
- To refine understanding of EPA's concepts and application of ERA guidelines for site assessment and remediation, especially to support the USACE HTRW program goals.

1.1.2 Scope

This guidance manual is not intended to be a "how to" manual which prescribes step-by-step procedures or instructions for preparing an ERA. Rather, the manual presents recommendations for scoping, managing, evaluating, and communicating to risk managers and other stakeholders the potential ecological risks posed by hazardous chemicals of ecological concern (COECs) at Resource Conservation and Recovery Act (RCRA) sites, Comprehensive Environmental Response, Compensation. and Liability Act (CERCLA) sites, and other sites managed under the HTRW program. This manual provides concepts for performing an ERA consistent with "good science" and accepted regulatory procedures. The following areas are not covered herein:

- Biological hazards - microbes (natural or genetically engineered) and other biological agents, including their use and impact to the indigenous species and environment.

- Radioactive hazards - radioactive wastes, radiation-generating devices, and radioactively contaminated materials.

- Study elements and regulatory requirements of a Natural Resource Damage Assessment (NRDA) -- (However, information presented in Chapter 2 of this manual could be helpful to HTRW sites mandated for NRDA actions.)

1.1.3 Intended Audience and Use

This manual is primarily for use by USACE personnel who are responsible for scoping, directing, and reviewing ERAS performed for HTRW response action sites. The guidelines provided herein are consistent with and should be considered in addition to existing EPA guidance contained in the *Risk Assessment Guidance for Superfund.* Volume *II, Environmental Evaluation Manual* (EPA 1989a), the *Framework for Ecological Assessment* (EPA 1992a), and the National Research Council's *Issues in Risk Assessment* (NRC 1994). The engineer manual entitled, *Technical Project Planning - Guidance for HTRW Data Quality Design* (USACE 1995b) should be reviewed, particularly for understanding the process described in Chapter 2 herein on how to determine data quality objectives (DQOs) to support an ERA.

The data collection, assessment, characterization of risk and uncertainty, and the risk management decision-making aspects presented in the following chapters are intended to satisfy RCRA and CERCLA regulatory requirements. The assessment of ecological risks under these two functionally equivalent programs is essentially the same. The concepts and assessment techniques presented below can be used to optimize data quality design across regulatory program requirements (if applicable) and justify or demonstrate that certain units or sites could be combined and assessed as a single entity according to the concept of establishing a corrective action management unit (CAMU) or temporary units (TU). If both regulatory programs are applicable at a site or unit, the ecological assessment components should be closely coordinated to avoid duplication of effort. Where possible, the technical and risk management approaches should be incorporated as specific language in agreements with EPA or states.

1.1.4 Contents of the Manual

- Chapter 1 presents the purpose, scope, concept, and science/policy considerations, and the use of ERA in HTRW programs. It provides a description of the USACE HTRW program, quality required for performance of an ERA, and an understanding of how ERAS serve management decision needs. Relevant Federal statutes/ regulations, agency guidance and directives, and state requirements are highlighted in this chapter.

- Chapter 2 presents the major scoping or project planning elements under CERCLA as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and RCRA as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Particular emphasis is placed on the early development of an ecological conceptual site model (ECSM) in the data quality design process to identify data needs, optimize data collection efforts, and recommend options for site decisions.

- Chapters 3 through 8 are intended to provide the risk assessor with the minimum requirements expected to be included in the ERA to adequately serve site decision requirements. They summarize the key components of the baseline ERA and other risk analyses. A running case study is presented throughout these chapters and Chapter 9 to explain key steps in an ERA and to demonstrate how risk management decisions may be made at each project phase in the HTRW program.

- Chapter 9 presents the information for risk management decision-making by focusing on the decision statements specific to the regulatory program and project phase, and criteria for decisions.

- Figures, tables, exhibits, and a continuous case study designed to illustrate or enhance readers' understanding of the materials are presented throughout. A glossary is presented also.

- Appendices A and B contain publication information for the references cited in the manual and additional sources of information, respectively.

Appendices C through H contain information that will be helpful to users of the manual in the prep aration of ecological risk assessments.

1.2 USACE Role in the HTRW Program

In the execution of USACE environmental missions, the HTRW program is organized and staffed to respond to assignments for the following national environmental cleanup programs:

- EPA Superfund Program (a.k.a. CERCLA).
- Defense Environmental Restoration Program (DERP):
  - Installation Restoration Program (IRP).
  - Formerly Used Defense Sites (FUDS).
  - Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program (DSMOA/CA).
- Base Realignment **and** Closure (BRAC).
- Environmental Compliance Assessment System (ECAS) (USACE 1992a).
- HTRW environmental restoration support for Civil Works projects and other Federal agencies (Department of Defense [DoD] and non-DOD).

For the purpose and intended use of this risk assessment manual, the focus is on the DERP and BRAC cleanup programs to address CERCLA- and RCRA-related issues.

1.2.1 DERP

DERP, codified in 10 USC Chapter 160, provides central program management for the cleanup of DoD hazardous waste sites consistent with the provisions of CERCLA. The goals of the program are: (1) the identification, investigation, research, and cleanup of contamination from hazardous substances: (2) correction of other environmental damage which creates an imminent and substantial endangerment to the public health and welfare, or to the environment; and (3) demolition and removal of unsafe buildings and structures.

1.2.2 BRAC

BRAC is an environmental restoration program with the mission to restore or clean up Army installations in preparation of real property disposal or transfer. The Base Closure Account (BCA), authorized under the Defense Authorization Amendments and Base Closure and Realignment Act of 1988 and the Defense Base Closure and Realignment Act of 1990, funds the BRAC program, which defines the nature and scope of contamination, performs remedial action, and documents the condition of real property by issuance of the Finding of Suitability to Lease (FOSL) (DoD 1993) and the Finding of Suitability to Transfer (FOST) (DoD 1994a). The Community Environmental Response Facilitation Act (CERFA) (Public Law 102-426) amends CERCLA Section 120(h) and requires Federal agencies to define "real property" on which no hazardous substances and no petroleum products or their derivatives were stored for one year or more. known to have been released, or disposed of before the property can be transferred. Transfer of contaminated property is allowed as long as the remedial action to clean up the site is demonstrated to be effective to EPA.

1.2.3 Others

Other components of the USACE HTRW program include:

- EPA Superfund Program Support -- Through an Interagency Agreement (IAG) and upon EPA request, USACE acts as the Federal government's contracting officer in conducting "Federal Lead" remedial design and construction activities. USACE may also provide other technical assistance to EPA in support of response actions.
- DSMOA/CA -- DoD reimburses states and territories up to one percent of the costs for technical services for environmental restoration cleanups. USACE is responsible for execution of activities which include establishing, managing, implementing, and monitoring the DSMOA/CA program.
- Non-Mission HTRW Work for Others -- Through IAG. non-DOD Federal agencies utilize the technical expertise and experience in work

relating to the RCRA, CERCLA, and underground storage tank (UST) investigation and response actions under the HTRW program for non-DOD Federal agencies.

- Guidance for Civil Works Projects -- The Civil Works districts may request technical support and guidance from HTRW program elements.

1.2.4 HTRW Program Organization

OM 10-1-1 (HQUSACE, October 31, 1990) and USACE HTRW Management Plan (USACE 1992b) describe the USACE organizational elements in support of DERP, BRAC, and other programs. Their major responsibilities include, but are not limited to, the following:

- The Assistant Secretary of the Army for Installations, Logistics, and the Environment (ASA (I,L,E)
- Headquarters, U.S. Army Corps of Engineers (HQUSACE) -- The Military Programs Directorate -- Environmental Restoration Division (CEMP-R) develops, monitors, coordinates, and proposes program management policies and guidance, and provides funding and manpower requirements to the program customers.
- The Director of Environmental Programs (DEP) within the office of the Assistant Chief of Staff for Installation Management (ACSIM) is responsible for interfacing with Department of Army (DA) components for policies and funds for IRP/FUDS/BRAC executed by USACE.
- HTRW Center of Expertise (CX) has the primary responsibility for maintaining state-of-the-art capability, providing technical assistance to other USACE elements, providing mandatory review of designated HTRW documents, and, as requested, providing technical and management support to HQUSACE.
- Ordnance and Explosives (OE) CX has the primary responsibility for maintaining state-of-the-art technical capabilities in OE, performing site inspections, engineering evaluations and cost analyses (EE/CA), and removal design phases of OE projects.
- Divisions are responsible for providing program oversight of all HTRW environmental restoration projects and designating project management assignments for HTRW projects.
- HTRW Design Districts provide the Division Commander with technical support in the areas of health and safety, chemical and geotechnical data quality management, environmental laws and regulations, risk assessment, contracting and procurement, and technical design and construction oversight.

1.3 Overview of HTRW Response Process

HTRW response actions involve all phases of a site investigation, design, remediation, and site closeout. The HTRW response process is generally comprised of six executable phases or steps, once the HTRW response site has been identified. They are:

- Preliminary Assessment (PA).
- Site Inspection (SI).
- Remedial Investigation (RI), including Baseline ERA.
- Feasibility Study (FS).
- Remedial Design/Remedial Action (RD/RA).
- Site Closeout.

The HTRW response action process is phased and performed in accordance with EPA procedures for assessing uncontrolled hazardous waste sites under CERCLA or RCRA. The following sections generally describe the CERCLA and RCRA processes, which are functionally equivalent to one another in objectives and types of site decisions to be made throughout each process.

1.3.1 CERCLA Process

CERCLA, commonly known as "Superfund," establishes a national program for responding to uncontrolled releases of hazardous substances into the environment. The regulation implementing CERCLA is the ***National Oil and Hazardous Substances Pollution Contingency Plan*** (NCP) (40 CFR 300, EPA 1990a). In general, the CERCLA process consists of the site assessment phase and the remedial phase as described below; however, removal actions (as allowed by the NCP) may be taken at any time during the CERCLA process. It should be noted that

the general framework established under the CERCLA process has been adopted for use in environmental cleanup under other programs, e.g., the cleanup of petroleum, oil, and lubricants (POLs) at FUDS or active installations not listed on the proposed or final National Priorities List (NPL). Therefore, certain CERCLA project phases described below (specifically, the Hazard Ranking System [I-IRS], NPL, and site deletion), are not applicable to these types of facilities.

1.3.1.1 Site Assessment Phase - To Identify Sites for Further Evaluation

- **Site Discovery** - EPA identifies and lists in the CERCLA Information System (CERCLIS) possible hazardous substance releases to be evaluated under Superfund.

- **PA** - While limited in scope, a PA is performed on sites listed in CERCLIS to distinguish sites which pose little or no threat to humans and the environment and sites that require further investigation or emergency response.

- **SI** - An SI identifies sites which (1) have a high probability of qualifying for the NPL or pose an immediate health or environmental threat that requires a response action, (2) require further investigation to determine the degree of response action required, and/or (3) may be eliminated from further concern.

- **HRS** - At the end of both the PA and SI, EPA applies a scoring system known as the I-IRS to determine if a site should receive a "no further remedial action planned" recommendation or be listed on the NPL for further action. An I-IRS can also be used to support other site evaluation activities under CERCLA (see ***The Revised Hazard Ranking System: Background Information,*** frtEPA 1990b). I-IRS scoring, however, is usually not applied at Federal facilities, especially for facilities within the IRP Program.

  DoD (1994b) has developed ***the Relative Risk Site Evaluation Primer*** to rank sites primarily for resource allocation and program management purposes. Although not a replacement nor alternative for I-IRS scoring, this model suggests that stakeholders consider evaluation factors (contaminant hazard factor, migration pathway factor, and receptor factor) to categorize sites according to "high," "medium," and "low."[1]

- **NPL** - Sites placed on the NPL (based on an HRS score of 28.5 or greater, state nomination, issuance of a health advisory by the Agency for Toxic Substances and Disease Registry (ATSDR), or other method) are published in the Federal Register and are eligible for Superfund-financed remedial action. DoD sites on the NPL. although not eligible for Superfund-financed remedial action, are eligible for Defense Environmental Restoration Account (DERA)-funded response actions.

1.3.1.2 Remedial Phase - To Determine the Degree of Risk Based on Nature and Extent of Contamination and Implement Cleanup Remedies if Warranted

- **RI** - The RI is a field investigation to characterize the nature and extent of contamination at a site and implement cleanup remedies if warranted. A baseline risk assessment, which includes both a human health risk assessment and an ERA, is performed as part of the RI. The baseline risk assessment is a component of the RI/FS report.

- **FS** - Based on data collected during the RI, remedial alternatives are developed, screened, and analyzed in detail. After potential alternatives are developed, the alternatives are screened against three broad criteria: effectiveness, implementability, and cost. Those alternatives which pass this initial screen will be

[1] *The Relative Risk Site Evaluation Primer* (DoD 1994b) has replaced the Defense Prioritization Model (DPM) which has features comparable to the HRS. DPM was used to predict whether the site may be a candidate for NPL listing or should receive priority funding under DERP.

further evaluated according to the nine criteria[2] and other risk management considerations not included in the criteria (e.g., environmental justice under Executive Order 12898) before one or more of such remedies is proposed for selection.[3]

- **Proposed Plan/Record of Decision (ROD)** - After the RI/FS process has been completed, a Proposed Plan is made available for public comment. The Proposed Plan identifies the remedies for the site jointly selected by the lead agency and the support agencies, and indicates the rationale for the selection. All final decisions and response to public comments are entered in a legal administrative record, the ROD.[4]

- **RD/RA** - RD is a subactivity in remedial implementation where the selected remedy is clearly defined and/or specified in accordance with engineering criteria in a bid package, enabling implementation of the remedy. RA is a subactivity in remedial response involving actual implementation of the selected remedy.

- **Five Year Review/Site Deletion** - Upon completion of all remedial actions, CERCLA and the NCP allows for the reclassification or deletion of the site from the NPL. If a remedial action results in any hazardous substances remaining on site, CERCLA Section 121(c) requires a review of the remedy once every five years to assure that: (1) the site is maintained, i.e., the remedy (including any engineering or institutional controls) remains operational and functional: and (2) human health/environment is protected, i.e., the cleanup standards (based on risk or ARARs) are still protective.

1.3.1.3 Removal Action - To Prevent, Minimize, Stabilize, or Mitigate Threat to Humans and the Environment

CERCLA Section 104 Removal Actions can take place at anytime during the entire CERCLA process. Unlike RAs, removal actions are not designed to comprehensively address all threats at the site. Removal actions may be emergencies (within hours of site discovery), time-critical (initiated within 6 months), nontime critical (planning for the removal action takes 6 months or longer), or early actions. Engineering evaluations and cost analyses (EE/CAs), comparable to FS, are required for removal actions that are deemed to be non time-critical.

1.3.2 RCRA Corrective Action Process

RCRA requires corrective action for releases of hazardous waste or hazardous waste constituents from Solid Waste Management Units (SWMUs) at hazardous waste Treatment, Storage and Disposal Facilities (TSDF) seeking an RCRA permit or approval of final closure. The owner or operator of a facility seeking a RCRA permit must:

- Institute corrective action as necessary to protect human health and the environment from all releases of hazardous waste and hazardous constituents from any SWMU at the facility.

- Comply with schedules of compliance for such corrective action.

- Implement corrective actions beyond the facility boundary.

The corrective action process has four main components: a RCRA Facility Assessment (RFA); a RCRA Facility Investigation (RFD; a Corrective Measures Study (CMS); and Corrective Measures Implementation (CMI).

- **RFA** - An RFA is designed to identify SWMUs which are, or are suspected to be, the source of a release to the environment. The RFA begins with a preliminary review of existing information on the facility, which may be followed by a visual site inspection. The RFA will result in one or more of these actions: (1) no further action is required: (2) an RFI is to be conducted to further investigate the documented

---

[2] The nine criteria are (1) overall protection of human health and the environment, (2) compliance with applicable or relevant and appropriate requirements (ARARs), (3) long-term effectiveness permanence, (4) short-term effectiveness, (5) reduction of toxicity, mobility, or volume, (6) implementability, (7) cost, (8) state acceptance, and (9) community acceptance.

[3] If the RI shows no unacceptable risk, regulators may agree to eliminate the FS and proceed directly to a no-action proposed plan.

[4] OSWER has published several Directives for RODs. Further information on these can be found in the USACE (1995b) Technical Project Planning Guidance document.

or suspected releases; (3) interim measures are necessary to protect human health or the environment: and (4) referral to other authorities to address problems related to permitted releases.

- **RF1** - An RFI may be required based on the outcome of the RFA. An RFI is accomplished through either a permit schedule of compliance or an enforcement order. The extent of this investigation can range widely from a small or specific SWMU study to an Area of Concern (AOC). Results of the RFI will result in one or more of these actions: (1) no further action is required; (2) CMS is necessary: (3) interim corrective measures are necessary; or (4) referral to another authority to address problems related to permitted releases.

- **CMS** - A CMS is an "engineering evaluation" designed to evaluate and recommend the optimal corrective **measure(s) at each SWMU or CAMU where** contaminant levels are found in excess of screening "action levels" (developed during the RFI). Medium-specific cleanup levels protective of human health and ecological receptors are developed, and the boundaries or point(s) of compliance are set. At this project phase or before the CMI phase, RCRA provides the designation of a CAMU or TU in which remediation wastes **may be moved and managed** (according to the approved corrective measures) without triggering land disposal restriction regulations under 40 CFR Part 268. The remedy selected from all potential remedial alternatives, including the "no further action" alternative, should be based on four criteria:

  - Protection of human health and the environment
  - Attainment of media cleanup standards
  - Control of sources to eliminate harmful releases
  - Compliance with RCRA's waste management and disposal requirements

- **CMI** - A CMI includes the actual design, construction, operation, maintenance, and periodic evaluation of the selected corrective measures.

EPA can impose interim corrective measures on RCRA facilities under corrective action to protect human health and the environment. The interim corrective measures can be taken at any time during the corrective action process.

EPA is accelerating cleanups at RCRA corrective action sites by promoting the reduction of exposure and further releases of hazardous constituents until long-term remedies can be selected. These accelerated cleanup actions are known as "Stabilization Initiatives" and are similar in concept and application to the Super-fund Accelerated Cleanup Model (SACM) under CERCLA.

1.3.3 Functional Equivalency of CERCLA and RCRA Corrective Action Processes

The RCRA and CERCLA programs use different terminology but follow parallel procedures in responding to releases. In both programs. The fist step after discovery of a site is an examination of available data to identify releases needing further investigation. This step is called PA/S1 in the CERCLA process and RFA in the RCRA process. If imminent human health and/or environmental threats exist, a mitigating action is authorized. known as a removal action under CERCLA Section 106 or an interim measure under RCRA Section 7003 or 3005(c)(3). Both programs require an in-depth characterization of the nature, extent, and rate of contaminant releases, called an RI in the CERCLA process and an RFI in the RCRA process. This is followed by a formal evaluation and selection of potential remedies in the FS (CERCLA) or CMS (RCRA) project phase. The selected remedy is executed by an RD/RA under the CERCLA process or CMI under the RCRA process. A specific discussion of the functional equivalency of both programs is presented in the preamble discussion of the July 27, 1990, proposed rules for Corrective Action for SWMUs at Hazardous Waste Management Facilities. A diagram comparing the RCRA and CERCLA processes is presented in Figure i-l.

1.3.4 Role of Risk Assessment in the HTRW Process

Performing an ERA is an iterative process. Risk assessment information is continuously being collected during the HTRW site investigation process, leading to the characterization of risks and uncertainties qualitatively or quantitatively. Risk assessment information is used in various stages of the HTRW site decision process as described below:

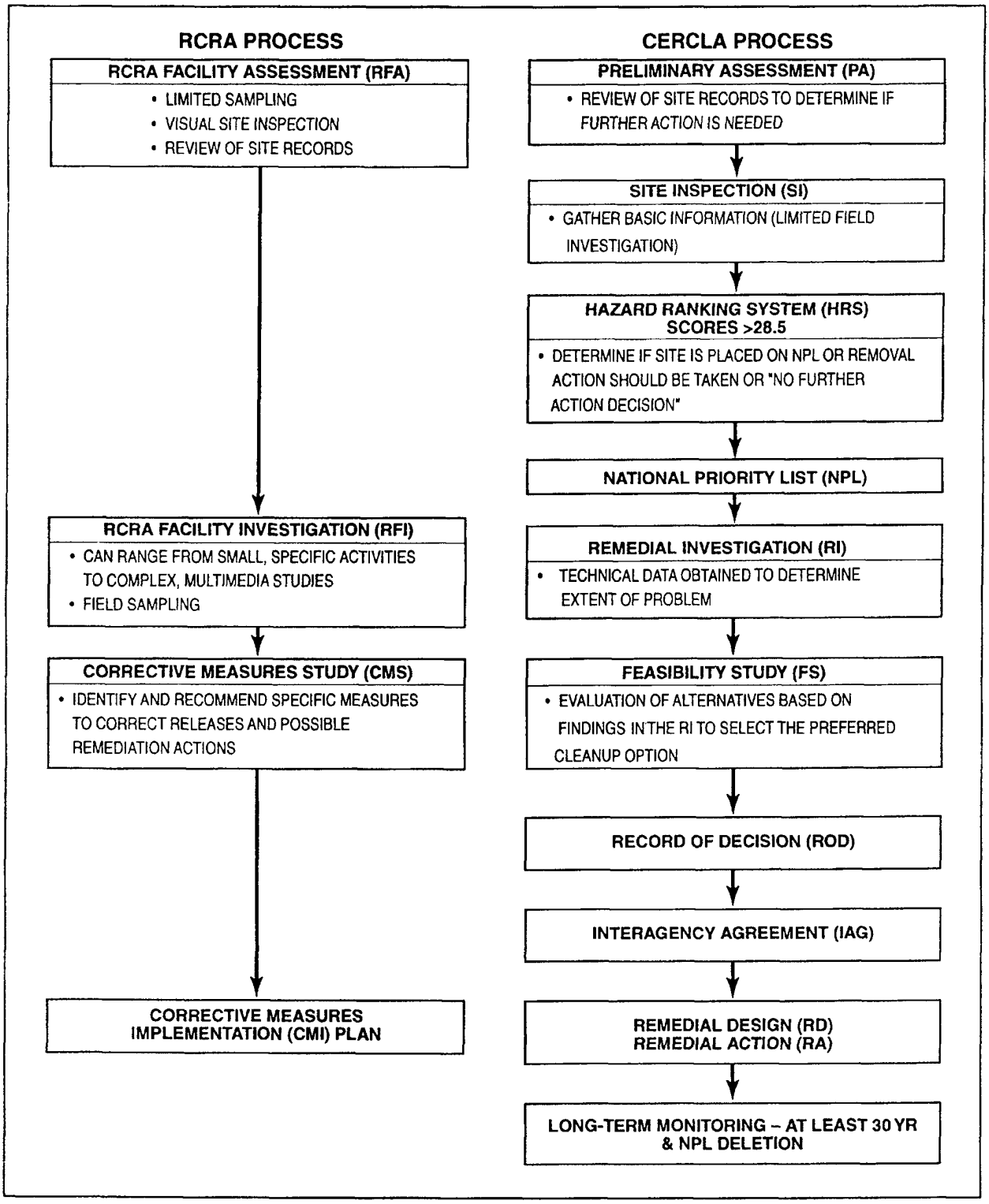


Figure 1-1. Comparison of RCRA and CERCLA processes

1.3.4.1 PA/SI, RFA, or Other Preliminary Site Investigation Activities

In this phase of the site investigation process, risk assessment information is used to: determine whether a site may be eliminated from further concern; identify emergency situations which may require immediate response actions/interim corrective measures: assess whether further site investigations are required; develop a data collection strategy; and set site priority, e.g., to rank sites.

The screening risk assessment developed during this phase should be conducted using conservative scenarios, as guided by the preliminary ECSM, to ensure that any closeout decision at the PA/SI stage is protective. The PA/SI ERA screening study is not to be confused with Preliminary Natural Resource Surveys (PNRSs), which are simple screening studies conducted by natural resource trustees in conjunction with an NRDA. If release of hazardous substances appears to have resulted in natural resource damage, then Section 122(j) of the amended CERCLA requires Federal natural resource trustees to be notified. Section 122(j)(1) encourages Federal natural resource trustees to participate in response and remedy negotiations, so that data collected in an ERA can be used by the trustees in carrying out their responsibilities.

1.3.4.2 RI, RFI, or Other Additional Site Investigation Activities

Data collected in this phase should comprise those media and pathways identified in the preliminary screening, including background data. If the data are useable and appropriate for the potential exposure pathways considered to be complete, a baseline ERA can be developed. The baseline ERA will identify whether unacceptable ecological risks are posed by existing conditions at the site.

For assessing ecological risks, data should be collected in the boundary or study area of ecological concern and may need to be collected in reference areas as well. The study area may necessitate combining SWMUs or operable units (OUs) or developing a base-wide ERA if such combination is consistent with the ECSM for assessing contamination and remediation options. Combined OUs or SWMUs should be discussed with the regulators and identified in the agreements with agencies, the work plan, or other decision documents.

1.3.4.3 FS, RD/RA, CMS/CMI, or Other Remedial Design and Implementation Activities

The baseline ERA completed in the RI serves to identify the need for response actions and the relative degree of response required. The potential human/environmental impacts posed during remediation (short-term and long-term) and the residual risks after remediation are evaluated during remedy selection.

1.3.4.4 Use of Risk Assessment in Special Studies

The following are examples of ERAs used in special studies:

- ARAR Waiver - If a site-specific alternate remedial action objective developed from the ERA is as protective as a particular ARAR. an ARAR waiver request may be submitted under CERCLA Section 121(d)(2). The same process may be used to waive state ARARs.

- Emergency Response - The effectiveness of a proposed removal action, particularly for non-time critical response action, can be evaluated by the ERA in terms of the ability of the action to reduce exposure or risks.

- Biological Assessment of Endangered Species - The Endangered Species Act (ESA) requires the preparation of a biological assessment if Federally listed endangered or threatened species or their habitat could be impacted by the contaminants or cleanup actions (e.g., incinerator emissions) at hazardous waste sites. The ERA for the endangered or threatened species, and optional assessment of the Category 2 and rare species, may satisfy the draft and final biological assessment requirements (Section 7 consultation) of U.S. Fish and Wildlife Service (USFWS) or other trustee agencies.

1.4 Concept of Risk Assessment and Good Science

Risk assessment can be qualitative or quantitative. It includes an integration of hazard (chemical or nonchemical), exposure (scenario and pathways), exposure-response (relationship between the magnitude of exposure and the

resulting ecological effects), and characterization of the risks and uncertainties. The risk assessment process relies on strong fundamental scientific principles and representative data. Despite this effort, there will be unavoidable data gaps and uncertainties where scientific and professional judgement is needed to predict or infer certain outcomes under certain scientific principles (Federal Focus Inc. 1994). The application of such judgement requires that the risk assessor provide the rationale or basis for the judgement. This view is reflected by the recent *Policy for Risk Characterization* (EPA 1995a) and *NRC's* (1993) *Science and Judgement in Risk Assessment.* Both EPA and NRC recognize the inherent uncertainties in the risk assessment methodologies and the need for making risk assessments more transparent, clear, consistent, and reasonable.

This section highlights the principles, instructions, or recommendations for assessing ecological risks from potential COECs[5] in environmental media at HTRW sites. A more in-depth discussion of the various risk assessment components and issues relating to HTRW response actions is presented in Chapter 4.

The fundamental principles of "good science" entail the thorough understanding of (1) site chemical data; (2) physical, chemical, and ecotoxicity information associated with site chemicals: (3) fate and transport modeling; (4) bioavailability and extent of uptake or bioconcentration; (5) the exposure-effects relationship of site chemicals and underlying uncertainties/conservatism; (6) uncertainties and limitations of the derived risk estimate: (7) the correct interpretation of previously collected data, considering confounding factors, and making objective inferences or test hypotheses; and (8) unbiased presentation of findings and limitations or uncertainties associated with the findings. This section concludes by identifying the minimum requirements for a risk assessment under the "good science" concept.

1.4.1 Basic Concepts

An open and unbiased ERA allows risk managers to make informed site decisions. The concept of "risk assessment" is presented in the following questions and answers:

What is a risk assessment?

A risk assessment is an evaluation of the potential adverse impact of a given activity or a lack of activity upon the well being of an individual, a population, a community, or an organization. It is a process by which information or experience concerning the cause and effect under a set of circumstances (exposure) is integrated with the extent of exposure in order to assess risk. RAGS II (EPA 1989a) defines an ERA as a qualitative and/or quantitative appraisal of the actual or potential effects of a hazardous waste site on plants and animals other than people or domesticated species (EPA 1989a). EPA (1994a) further defines an ERA as an estimate of the likelihood that adverse ecological effects (e.g., mortality, reproductive failure) will occur as a result of a release of a hazardous substance at a Superfund site. EPA (1994a) states the purpose for conducting the ERA is to "(1) identify and characterize the current and potential threats to the environment from a hazardous substance release, (2) evaluate the ecological impacts of alternative remediation strategies, (3) establish clean-up levels in the selected remedy that will protect those natural resources at risk."

Generally, an ERA consists of a three-step process:

- **Problem Formulation** - specify objectives and scope; identify preliminary remediation goals; qualitatively evaluate contaminant release, migration, and fate; identify potential COECs, exposure pathways, receptors, and known effects: develop a preliminary ECSM: and select ecological endpoints.

- **The Analysis Phase,** which is comprised of two major elements:

  - **Exposure Characterization** - quantify contaminant release, migration, and fate: characterize receptors: measure or estimate exposure point concentrations: and refine the ECSM regarding the relationships among trophic levels in the food web model.

  - **Effects Characterization Assessment** - review ecotoxicity information from

[5] Chemicals of potential ecological concern (COPEC) may also be used instead of potential COECs. The term "potential" should be used throughout the course of the ERA, until the chemicals are determined to be or not to be of concern. In this manual, the term potential is generally implied wherever COEC is used.

literature, toxicity testing, and field studies: and assess nonchemical impacts or potential adverse health impacts from remediation.

- **Risk Characterization** - present findings qualitatively or quantitatively with regard to the potential impacts to individuals, populations, communities, or other ecosystem components of concern from a single chemical or multiple chemicals from one or more site media, based upon the review of exposure assessment and exposure-response information. A candid discussion of the uncertainty associated with the risk characterization findings is an essential component of this step. This step focuses on the significance of the impact, causal association or weight-of-evidence, and sources of uncertainty.

Why use risk assessment in site decisions?

- Risk assessment can identify sites in the SI or RFA stage that warrant no further evaluation.
- Risk assessment provides a tool that enables risk managers to determine if remediation is warranted and to prioritize those sites requiring remediation.
- CERCL/SARA requires that remedial actions assure "protection of human health and the environment" against contaminants that "will, or may reasonably be anticipated to cause" certain adverse health effects, and must under certain circumstances meet standards set under other Acts..." The NCP provides for the use of risk assessment in removal actions, remedial actions, and remedy selection. Consistent with the NCP, the SACM at EPA requires site screening, risk assessment, and early action to reduce immediate risk for removal/immediate response actions.
- RCRA/HSWA establishes EPA programs to control disposal of solid wastes which "may cause, or significantly contribute to an increase in mortality or... serious irreversible, or incapacitating reversible, illness; or . . . pose a substantial present or potential hazard to human health or the environment" or which "endanger health [when present in excess of certain levels]." The RFI Guidance (EPA 1989b) provides general procedures for performing a health assessment and an environmental assessment. The Corrective Action Rule (RCRA Subpart S) also provides the use of a site-specific risk assessment to evaluate SWMUs or the CAMUs under enforcement actions or Part B permitting.

What are the minimum requirements of information **in the risk assessment?**

- Specification of which chemicals are of particular concern from an ecological perspective and what are the mechanisms for their release and transport (chemical abstract numbers should be provided).
- Environmental setting, and potential/reasonably anticipated land use.
- Potential receptors and populations, and the relationships of organisms/populations among different trophic levels in a community or ecosystem.
- Complete and significant exposure pathways.
- Reasonably assumed chemical uptake, bioaccumulation in the individual and biomagnification in the ecosystem under short-term and long-term exposure conditions.
- Adverse ecological effects for ecological receptors that are measurable and can be appropriately related back to the assessment endpoints.
- Uncertainties and limitations of the risk assessment, expressed either qualitatively or quantitatively.
- Chemicals and exposure pathways which contribute the most risk (pose the principal threat).
- Protectiveness of remediation goals and health impacts of the removal/remediation actions.

Throughout this manual, there are references to uncertainties in a risk assessment and the use of good science to plan and execute a site-specific baseline ERA. Clarifying the meaning of these terms will help readers who are responsible for scoping, planning, and reviewing a baseline risk assessment. The existence of uncertainties in a risk assessment and the importance of good science are explained in the following questions and answers:

How do "uncertainties" impact a risk assessment?

- The application of sound scientific principles is critical to assessing risks. Only rarely do sufficient data exist to accurately define the extent of exposure and the resulting ecological effects. Therefore, an ERA is frequently performed with assumptions, empirical models, extrapolations, test of hypotheses, and inferences of results which have a certain level of uncertainty. Many times, conservative assumptions are used in models relating to exposure and toxicity that characterize ecological risk. These assumptions add another degree of uncertainty to risk assessment. For these reasons, the predicted ecological effects experienced by the individuals, populations, and/or community could be higher than the current or future observed effects. This conservatism may unnecessarily result in environmental cleanup with little or no measurable environmental benefits and can divert resources from higher priority projects.

What is meant by "good science" in a risk assessment?

- Risk assessment as a "scientific" endeavor should be objective to assure that the assessment is specific to the site, is based on sound scientific principles, and is defensible. However, a risk assessment often requires use of "professional judgement" when data are lacking, lends itself to interpretation, often uses assumptions and generalities, and may easily become nonobjective. Bias or lack of scientific objectivity can cause the risk results to over- or under-estimate the true risks. This may result in costly delays or inappropriate inaction/action. Therefore, a peer review process should be incorporated in various phases of the risk assessment, and care should be given early in the scoping and planning process to collect data and specify requirements in performing a risk assessment under the HTRW program. Persons performing the risk assessment should have a good understanding of the site and should possess the basic skills needed to plan, collect, and interpret the information.

1.4.2 Risk Assessment as Decision Criteria in the HTRW Program

The role of a risk assessment in the site decision-making process at CERCLA and RCRA Corrective Action sites has been well defined by EPA either through rule-making or program directive/guidance. Therefore, risk assessments have been used as decision criteria in the USACE's HTRW program involving CERCLA and RCRA sites. For BRAC, FUDS, or other HTRW work which may not be on the NPL, risk assessments should be similarly applied. Activities at these sites require the evaluation of potential health and environmental risks in order to return the property to conditions appropriate for the current and planned future land uses. Therefore, a site-specific baseline risk assessment is an important decision tool for USACE customers. If cleanup is needed, the extent or level of cleanup required will be based on results of the baseline risk assessment, in addition to ARARs or other nonrisk factors. Therefore, risk assessment is used as a decision tool at all HTRW response action sites.

DoD and other Federal agencies recognize the need for early input from all stakeholders (broadly defined as the regulators, concerned citizens, environmental groups, and other appropriate public and private interested parties) in order to facilitate risk management decision-making. Establishing an early dialogue with stakeholders is particularly important for ERAS in the project planning phase to develop assessment strategies and preliminary remedial action objectives.

1.5 Policy Considerations and Risk Management

This section presents a general discussion of the influence of policy considerations in risk assessment and risk management. Because of the implications of policy considerations on the site decision process, the risk assessors and risk managers are encouraged to identify the policies early in the decision process.

Unlike regulations which are enforceable, policies or published guidelines are administrative procedures or requirements concerning certain environmental regulations. DoD has issued directives to components (Army, Navy, Air Force, Defense Logistic Agency, and Defense Nuclear Agency), reaffirming DoD's commitment to comply with specific environmental laws or executive orders. The respective components have also issued directives or orders expressing the same procedures or requirements. USACE will follow such policies or directives issued by DoD or its components regarding compliance with Federal environmental laws in the execution of HTRW response action at DoD installations or facilities. Some states or regional environmental control boards have also issued environmental policies or guidance. In the unlikely event that a policy is scientifically incongruent with site situations, early identification and

resolution are critical. HQUSACE or HTRW CX technical staff should be consulted in these instances. All major policies used in making site decisions should be identified in the ROD or site decision documents so that the USACE customers and other stakeholders can judge the merit of these policies in achieving protection of human health and the environment.

1.5.1 Relationship Between Policy Considerations and Risk

A risk assessment is the technical evaluation of the degree of hazard or risk associated with exposure of a receptor or receptor populations to contamination of an environmental medium or media. Risk management is oriented toward deciding whether remedial actions are warranted in light of the results of a risk assessment. The National Academy of Sciences (NAS) National Research Council (NRC) defines risk management as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NRC 1983). NAS has identified four key components in managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994).

In making risk management decisions, the risk manager considers the degree of risk, technical feasibility to address risk, costs and benefits, community acceptability, permanence of the proposed actions, and other similar factors which are subject to policy considerations or regulatory requirements. As such, risk management is an important part of the USACE HTRW site response process, as it combines results of the risk assessment, regulatory requirements, and applicable agency policies (e.g., applicable DoD policies for defense sites).

1.52 EPA Headquarters, Regional, and State Policies

To successfully complete a risk assessment for use in making site decisions, HTRW project managers and risk assessors generally work with Federal, regional, and state regulatory agencies to identify their specific policies or procedural requirements. HTRW risk assessors should identify and assist, where appropriate, in negotiations with the agencies on policies, procedures, and assumptions which are questionable.

All HTRW response actions should be in compliance with the Regulatory Policy Guideline issued under Executive Order 12498 (1985) Government Management, which states, "Regulations that seek to reduce health or safety risks should be based upon scientific risk assessment procedures, and should address risks that are real and significant rather than hypothetical or remote." USACE's HTRW position should be supported by scientific principles, site data, or literature values, whenever possible. USACE recognizes that at times, agencies have to set policies in the absence of scientific consensus: however, USACE, through the HTRW program, has the responsibility to apply such policies properly and objectively based on site-specific considerations.

1.5.3 Risk-Based Management Decisions for Site Actions

Risk managers select the most appropriate remedy by considering "trade-offs" among different remedial alternatives and evaluating the ability of the alternatives to accomplish the overall project objectives. To improve the quality of risk-based management site decisions, HTRW risk assessors should identify key information that can affect that decision-making. This information should include policy considerations, assumptions concerning the margins of safety, and the use of other relevant data not associated with the site in the risk assessment. The sources of such policies and data, as well as the qualifications of persons/organization recommending the policies or use of data, should be clearly identified. HTRW risk assessors can further help risk managers by providing an explanation of uncertainties in the risk assessment. When science deviates from policies or assumptions inherent in the risk assessment, it is the responsibility of HTRW risk assessors to clearly identify these instances as potential uncertainties as well.

1.6 Regulatory Directives and Guidance

This section highlights major executive orders, Federal statutes/regulations under which the HTRW programs operate, and EPA risk assessment guidelines which provide the basis for development of this manual. Irrespective of the procedures or mechanics for conducting risk assessments according to regulatory guidelines, all risk assessments performed under the HTRW response action must be based on "good science" and reasonable and unbiased scientific judgment. Although this section lists only major applicable executive orders and directives, others may be accessed through the appropriate agencies and databases on Internet (see Appendix B).

1.6.1 Executive Orders and Federal Statutes/ Regulations

Executive Order 12088 (1978). ***Federal Compliance with Pollution Control Standards,*** established the mechanism by which the Executive Branch assures that its facilities (in various departments) meet their compliance responsibilities by complying with substantive and procedural requirements of Federal environmental statutes. These statutes include: Endangered Species Act (ESA), the Clean Air Act (CAA); the Federal Water Pollution Control Act (Clean Water Act): the Solid Waste Disposal Act (as amended by RCRA); the Noise Control Act: the Marine Protection, Research and Sanctuaries Act (Ocean Dumping Act), the Safe Drinking Water Act (SDWA), the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the National Historic Preservation Act (NHPA), and the National Environmental Policy Act (NEPA).

Executive Order 12498 (1985), ***Government Management,*** incorporates by reference the regulatory principles contained in a Task Force report regarding future significant regulatory actions. Two principles of interest are:

- Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant, rather than hypothetical or remote.

- To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessment must be unbiased best estimates, not hypothetical "worst cases" or "best cases." ... In addition, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

Executive Order 12580 (1987). ***Superfund Implementation,*** requires all Federal agencies to comply with CERCLA/ SARA and NCP in the same manner as the private sector. This Order delegated to the Secretary of Defense the response authority of DoD, which includes removal/ remedial actions, site investigation and risk assessment, remedy selection, performance of PAs, and assuming natural resource trustee's responsibilities for current and former DoD facilities, and others. The Office of the Deputy Under Secretary of Defense for Environment Security (ODUSD [ES]) is responsible for carrying the Secretary's responsibilities and administering DERPs in compliance with this Order.

Executive Order 12777 (1991). ***Implementation of Section 311 of the Federal Water Pollution Control Act of October 18, 1972 and the Oil Pollution Act of*** 1990. Delegates to the EPA and Coast Guard various responsibilities assigned to the President under Clean Water Act Section 311 and the Oil Pollution Act of 1990.

Other relevant Executive Orders include: Executive Order 11990 (1977), ***Protection of Wetlands,*** and Executive Order 11988 (1977), ***Floodplain Management.***

NEPA 1969 provides a national framework for the protection of the environment by requiring compliance with a wide variety of existing environmental statutes. It mandates the Federal agencies "utilize a systematic, interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision-making, which may have an impact on man's environment." The implementing regulations for NEPA am found in 40 CFR 1500-1508, as promulgated by the Council on Environmental Quality.

It is, in essence, a planning tool for nonemergency environmental actions, through either justifications for categorical exclusions or through preparation and approval of NEPA documents (i.e., environmental assessment [EA] and environmental impact statements [EISs]). The NEPA documents evaluate alternatives and provide analysis on alternatives regarding their impacts on health, safety, and welfare of humans and the environment, including environmental justice in minority and low income populations. HTRW response actions, specifically removal and remedial actions, could be subject to NEPA review for the selection of alternatives. The implementing guidance for DoD for NEPA includes:

- DoD Directive 6050.1 (July 30, 1979a), ***Environmental Effects in the United States of Department of Defense Actions.***

- DoD Directive 6060.7 (March 31, 1979b), ***Environmental Effects Abroad of Major Department of Defense Actions.***

- Army Regulation 200-2 (1988), ***Environmental Effects of Army Actions.***

RCRA 1976, as amended by the HSWA of 1984, has the objectives to protect human health and the environment,

reduce waste and conserve energy/natural resources, and reduce or eliminate generation of hazardous waste:

- Subtitle D - solid waste (encourages states to develop and implement solid waste management plans to provide capacity).

- Subtitle C - hazardous waste program (identifies hazardous wastes and regulates their generation, transportation, and treatment, storage, or disposal; authorizes states to implement the hazardous waste program in lieu of EPA: requires permits for TSDFs).

- Subtitle I - underground storage tanks (regulates petroleum products and hazardous substances stored in underground tanks: requires compliance with performance standards for new tanks: and requires leak detection, prevention, closure, financial responsibility, and corrective action).

CERCLA of 1980, as amended by the SARA of 1986 (42 U.S.C. 9601 et seq.) provides broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. SARA defines the process Federal agencies must follow in undertaking remedial action, including a requirement that EPA make the final selection of remedy if there is a disagreement between the Federal agency and EPA.

The NCP (55 FR 8660, 9 March 1990) provides procedures and standards for how EPA, other Federal agencies, states, and private parties respond under CERCLA to releases of hazardous substances. The NCP authorizes the U.S. Department of the Interior (USDOI) and other agencies, states, or entities to be the "trustees" of natural resources to recover compensatory damages for "injury to, destruction of, or loss of natural resources resulting from a discharge of oil into navigable waters or a release of a hazardous substance."

Federal Facility Compliance Act (PL-102386. October 21, 1992) directs Federal agencies to comply with Federal and state environmental laws, and provides authority to EPA to impose penalties on other Federal agencies for noncompliance. Among others, it amended Section 6001 of RCRA to waive immunity of the United States (Federal department, agency, or instrumentality of the United States) to administrative orders and civil penalties or fines associated with Federal, state, interstate, and local solid and hazardous waste management requirements. Section 3004 of RCRA was also amended to require EPA, in consultation with DoD, to identify and regulate waste military munitions which are hazardous.

1.6.2 DoD Directives

DoD Directive 5100.50 (19731, ***Protection and Enhancement of Environmental Quality,*** establishes procedures and assigns responsibilities for use of DoD resources in the protection and enhancement of environmental quality and establishes the DoD Committee on Environmental Quality.

DoD Directive 5030.41 (1977a), ***Oil and Hazardous Substances Pollution Prevention and Contingency Program,*** sets forth DoD policy in support of the NCP.

DoD Directive 4120.14 (1977b) ***Environmental Pollution, Prevention, Control, and Abatement,*** implements within DoD new policies provided by Executive Order 12088 and Office of Management and Budget (OMB) Circular A-106, and establishes policies for developing and submitting plans for improvements needed to abate air and water pollution emanating from DoD facilities.

DoD Directive 6230.1 (1978), ***Safe Drinking Water, sets*** forth DoD policy for provision of safe drinking water and compliance with the SDWA.

DoD Directive 6050.1 (1979a), ***Environmental Effects in the United States of DoD Actions,*** implements the CEQ regulations and provides policies and procedures to take into account environmental considerations in DoD actions.

1.6.3 EPA Headquarters and Regional Guidance

CERCLA

Guidance documents (OSWER Directives) for conducting various phases of a CERCLA response action have been developed or are being finalized by EPA headquarters. Key CERCLA guidance documents are identified below (also see Appendix B):

- ***Guidance for Performing Preliminary Assessments Under CERCLA*** (EPA 199 la). This document provides the PA objectives, data requirements, the procedural steps to complete the PA, and develops a site score using PA scoresheets. It also provides guidelines for reviewing the site evaluation and score, including identification of sites for emergency response actions.

- *Guidance for Performing Site Inspections Under CERCLA* (EPA 1992b). This document provides the approaches, data acquisition planning needs, sampling strategies, data evaluations using the SI worksheets, and reporting requirements for the CERCLA SI. The document describes the approach of use of a focused SI to test the PA hypotheses, resulting in one of three recommendations: (1) site evaluation accomplished: (2) expanded SI to collect additional data: or (3) preparation of an FIRS package for placement of the site on the NPL if the HRS scoring data requirements have been met.

- *Hazard Ranking System Guidance* (EPA 1992c) provides guidance to individuals responsible for preparing HRS packages for sites for inclusion on the NPL.

- *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, interim final* (EPA 1988a). This guidance describes the CERCLA RI/FS process to characterize the nature and extent of contamination or risks posed by a site and to evaluate whether remedial action is needed. It describes the site characterization techniques, the role of a baseline risk assessment, feasibility studies, and development of screening and detailed analyses of remedial alternatives.

- *Guidance for Data Useability in Risk Assessment (Part A)* (EPA 1992d) and (Part B) (EPA 1992e). These guidance documents provide approaches and recommendations for defining, planning, and assessing analytical data for the baseline risk assessment.

- *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual* (RAGS II) (EPA 1989a) - The guidance consists of two parts: (1) a guidance manual that establishes a general framework for understanding the ecological principles of a Super-fund ERA and discusses the performance of the assessment, and (2) a compendium method handbook, *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference* (EPA 1989c).

- *Eco Update* - Eco Update is a bulletin series on ecological assessments at Superfund sites. These bulletins serve as supplements to RAGS II and share information with the readers advisories involving the Biological and Ecological Technical Assistance Groups (Biological Technical Assistance Groups [BTAGs], Ecological Technical Assistance Groups [ETAGs]), and other ERA and natural resource issues. The bulletin series is written for both general and technical audiences.

- *BTAG Forum* - BTAG Forum is a bulletin series published by EPA/OERR primarily to foster communication among BTAGs/ETAGs in EPA Regional Offices. The Forum carries news from the Regions, information on publications and other potentially useful resources, requests for information, and other items of interest to BTAG members.

- *Superfund Program Checklist for Ecological Assessment/Sampling* (EPA 1993a) - This checklist provides guidance on making observations during an ecological assessment and is a screening tool for preliminary site evaluation. The checklist is not intended to be used for limited actions nor for purely industrial settings with no discharges, but may be useful in planning more extensive site investigations.

- EPA Regional guidances - A number of EPA Regions and states have developed ERA guidance and specific protocols or approaches. Risk assessors should consult with the individual EPA Regions or states to obtain their specific guidances. For example, EPA Regions V and VI have published regional ERA guidance (EPA 1992f; EPA 1991b); EPA (1994b) Region III has issued *Interim Ecological Risk Assessment Guidelines:* and EPA Region IX is developing protocols for the evaluation of terrestrial indicators.

RCRA

Limited guidance has been developed for conducting various phases of a RCRA facility response action to address current or past releases. The key RCRA guidance documents that are available are identified below:

- *RCRA Facility Assessment Guidance* (EPA/530-SW-86-053) (EPA 1986a). Provides guidance for conducting facility assessments to reflect developments of the RCRA corrective action programs. Also clarifies the definition of an SWMU.

- *RCRA Corrective Action Interim Measures Guidance* (EPA/530-SW-88-029) (EPA 1988b). Assists EPA regions and states to perform corrective action interim measures to mitigate or remove an exposure threat presented by releases.

- *RCRA Corrective Action Plan* (EPA/530-SW-88-028) (EPA 1988c). Provides technical framework for development of Corrective Action Orders and corrective action permit requirements.

- *RCRA Facility Investigation (RFI) Guidance* (EPA 1989b). General guidelines for performing health and environmental evaluations are described in this four-volume guidance manual. With regard to performing environmental risk assessments, this guidance is substantively equivalent to RAGS and references the CERCLA methodology.

1.6.4 State Requirements/Guidance

HTRW risk assessors and project managers need to be aware of any risk assessment procedures, data needs, or programs specific to the state in which their site is located. Almost all states have been authorized for RCRA permitting: some have corrective action authorities. Many states have statutes and regulations that address uncontrolled hazardous waste sites and SWMUs associated with regulated RCRA facilities. Also, many states have primacy in the water pollution control program (under CWA) and have either adopted EPA criteria or developed their own water quality standards. Many states have adopted the use of risk assessment for corrective action, to demonstrate "how clean is clean," to develop site-specific cleanup goals, to evaluate facilities burning hazardous waste, or for other uses.

Some states have developed specific guidance for assessing environmental impacts. For example, the New York Department of Environmental Conservation (NYDEC 1991) has developed *Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites. Environmental Risk Characterization Guidance* is available from the Massachusetts Department of Environmental Protection (MDEP 1994). California Environmental Protection Agency has also developed its own guidance entitled, *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities* (CAL EPA 1994). Pennsylvania's Department of Environmental Resources (1991) has developed *Risk Assessment Guidelines for Facilities Burning Hazardous Waste.* Other states (Connecticut, Illinois, and Kentucky) have adopted RAGS II, and in some cases, EPA regional guidance, as a matter of policy.

In addition to state rules, regional initiatives may exist that may need to be considered when performing an ERA. For example, EPA (1995b). in coordination with the Great Lakes states, undertook the Great Lakes Water Quality Initiative (GLWQI) and published the *Final Water Quality Guidance for the Great Lakes Systems (60 FR* 15366). The guidance specifies water quality criteria for the Great Lakes as well as specific water program requirements. The purpose of the guidance is to establish consistent water quality criteria within waters of the Great Lakes basin.

1.6.5 Others

U.S. Army (USA)

Army Regulation 200-l. *Environmental Quality, Environmental Protection, and Enhancement* (USA 1990). implements the Federal environmental laws and regulations at the Department of the Army facilities. Chapter 12-5. Army Regulation 200-1 requires the performance of an Environmental Baseline Study for any property transaction. DA PAM 40-578 (USA 1991). entitled *Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites,* presents the methodology used by the Army when reviewing health risk assessments, and designates the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) to oversee and recommend approval or disapproval to the Army Surgeon General on all human health risk assessments prepared by executing agencies for Army IRP sites, BRAC sites, and FUDS.

The U.S. Army Edgewood Research, Development, and Engineering Center (USAERDEC) (formerly the U.S. Army Chemical Research, Development, and Engineering Center) has developed the *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994). This guidance develops a standardized ERA procedure and tiered approach for assessing ecological risks.

Army Regulation 420-74, *Natural Resources -- Land, Forest, and Wildlife Management, p*rovides Army policy for managing natural resources and attaining the goal of ensuring that Army actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species.

U.S. Air Force (USAF)

The Office of the Air Force Surgeon General's Biomedical Engineering Service (BES) is responsible for providing technical support for all Air Force DERP CERCLA activities. The Air Force *Installation Restoration Program Management Guidance* (USAF 1989) and FY 93/94/95 *DERA Eligibility and Programming Guidance* (USAF 1992) provide guidance in this area. Work relating to hazardous waste management activities under RCRA is performed by the BES in accordance with Air Force Regulation 19-7 and *USAF Hazardous Waste Management Policy* (USAF 1991). Currently, the environmental service centers for USAF, such as USACE, or the risk assessors at respective Major Air Force Commands (MACOMs) review risk assessments in coordination with the Air Force Surgeon General.

The Human System Division IRP Office at Brooks Air Force Base, Texas, has developed the *General Guidance for Ecological Risk Assessment at Air Force Installations* (USAF 1990). The document provides an overview of the fundamentals of risk assessment and guidance for conducting an ERA. Guidance is provided for assessing the terrestrial, freshwater, and marine habitats.

U.S. Navy and Marine Corps

The Chief of Naval Operations directive OPNAVINST 5090.1B (DON 1994), Department of the Navy (DON), assigns command responsibilities and provides Navy policy to comply with environmental laws and regulations. The Navy and Marine Corps IRP Manual (DON/CNO 1992) describes the Navy organization/responsibilities in support of IRP, priority for funding, research, training, and reporting requirements including preparation of Pollution Control Report to satisfy the OMB Circular A-106 reports to EPA. The Naval Environmental Health Center, under the direction of the Bureau of Medicine and Surgery (BUMED), provides a wide range of medical consultative services to the Naval Facilities Engineering Command community in support of the IRP, the BRAC Program, and other related environmental projects. Consultative support services include but are not limited to review of IRP and BRAC program documents (e.g., work plans, sampling and analysis plans, quality assurance/ quality control plans: remedial investigation/feasibility studies, risk assessments, health and safety plans) from a risk assessment and public health perspective: conducting risk evaluations or quantitative risk assessments; training in risk assessment, public health assessment, health and safety plans, and risk communication: sponsoring the 3-day tri-service Environmental Risk Communication and Public Dialogue Workshop: negotiating with regulators regarding the use of realistic exposure assumptions; assisting in developing community relations plans: assisting in establishing Restoration Advisory Boards (RABs); assisting in preparing correspondence from a risk communication perspective; preparing posters for public exhibits and public meetings; and acting as the DON liaison for ATSDR issues.

U.S. Environmental Protection Agency (EPA)

EPA has published a number of enforcement policies and procedures for Federal facilities, e.g., *Federal Facilities Compliance Strategy* (EPA 1988d), *Enforcement Actions Under RCRA and CERCLA at Federal Facilities* (EPA 1988e), *Evaluation Process for Achieving Federal Facility Compliance* (EPA 1988f), *Federal Facilities Negotiations Policy* (EPA 1989d), and *Federal Facilities Hazardous Waste Compliance Manual* (EPA 1990c). All Federal agencies are required to comply with hazards waste regulations and the NCP in the same manner as the private sector. EPA has published numerous guidance and resource documents applicable to ERAs. Many of these references are presented in Appendix B.

U.S. Department of Energy

DOE has issued a number of orders (5400 series and others) addressing a variety of environmental statutes and requiring all DOE facilities to comply with applicable environmental laws and regulations. Some of the key DOE guidances are included in Appendix B.

U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA)

NOAA has published a manual entitled *The Coastal Resource Coordinator's Bioassessment Manual* (NOAA 1992). As a desk reference manual for coastal coordinators, this manual provides general guidelines on the application of bioassessment procedures to different stages of the hazardous waste site remedial process, the design of bioassessment studies, and use of specific bioassessment methodologies. In addition, a summary of recommended aquatic toxicity testing protocols is provided. NOAA (Long et al. 1995) has also published screening levels for chemical concentrations in marine sediments, based on studies at multiple sites in the marine and estuarine environments.

Canadian Council of Ministers of the Environment

Environment Canada (1994) has published a *Framework for ERA* and sediment screening values (CCME 1995). The Canadian province of Ontario has published sediment lower effect level (LEL) and severe effect level (SEL) values for the evaluation of marine and freshwater sediments (Persaud, Jaugumagi, and Hayton 1992, Long et al. 1995).

USFWS

USFWS published the Contaminant Hazard Review series between 1985 and 1994. This continuing series of reports reviews the hazards of specific toxic compounds to invertebrates and wildlife. Biological Report 90(2) summarizes data on soil toxicity for screening assessment for terrestrial systems (Beyer 1990).

Water Environmental Research Foundation (WERE)

WERF (1994) has developed the *Methodology for Aquatic Ecological Risk Assessment* which embraces established methodologies developed by the Federal agencies, national laboratories, and private institutions, and contains new, original procedures. The guidance is intended to assist members of the regulated and regulatory communities who need to estimate the effects of toxic chemicals on aquatic communities from new point or nonpoint sources of chemicals, improved wastewater treatment, discharge changes from an existing wastewater treatment facility, and hazardous waste site cleanup or remediation.

USGS

The U.S. Geological Survey (USGS) offers numerous publications on topics relevant to ecological risk assessment (e.g., background water chemistry).

1.7 Federal Facility Agreement

Although there may be subtle differences between a Federal Facility Agreement (FFA) and an IAG, these terms are used interchangeably under CERCLA Section 120 which addresses both NPL and non-NPL sites. This section focuses on the need for early planning and negotiation of an FFA among the USACE customer (a Federal agency), EPA, and the state agency (as appropriate). To accomplish this objective, the HTRW project team member (i.e., the risk assessor) and others should work cooperatively to develop statements/languages or addenda to the FFA early in the HTRW project cycle to define a flexible framework or process for risk management decision-making and to facilitate a site closeout protective of human health and the environment.

Executive Order 12580 delegates DoD to conduct response action under Section 104 of CERCLA (as amended by SARA) to address releases on DoD facilities or originating from the facilities. The order requires that the response action be conducted in accordance with Section 120 of CERCLA. According to CERCLA Section 120(e)(l), DoD is directed to enter into an IAG with EPA for remedial action within 180 days of EPA's review of the RI/FS. The *Federal Facilities Hazardous Waste Compliance Manual* (EPA 199Oc) states, "At a minimum, the IAG must include a review of cleanup alternatives considered and the remedy selected, a schedule for cleanup accomplishment, and arrangements for operation and maintenance" (EPA 1990e).

To address noncompliance issues at a Federal facility (e.g., a DoD installation), EPA may issue a complaint known as Notice of Noncompliance (NON). After such an issuance, EPA and the Federal facility enter into negotiation for a Federal Facility Compliance Agreement (FFCA) which resolves compliance violations and stipulates agreed-upon remedy, compliance schedule, and reporting and recordkeeping requirements. The target date for concluding such an agreement is within 120 days from the date of NON issuance (EPA 1990c). Since RCRA corrective actions are generally required at the time of RCRA Part B permitting or permit renewal, the Federal facility may be issued a RCRA Section 3008(h) corrective action order rather than a NON.

In recent years, model language has been developed to facilitate agreement among the Federal agency, EPA, and the state agency (if applicable) to identify milestones, schedule, requirements, and dispute resolution procedures pertaining to investigation and cleanup at CERCLA and RCRA sites. In the Federal Facility Compliance Agreement (FFCA) of 1992, Federal agencies are no longer afforded with "sovereign immunity" from compliance with state and Federal environmental laws. In the opinion of the Department of Justice (DOJ). however, executive branch agencies may not sue each other nor may one issue an administrative order to another without providing a prior opportunity to contest the order within the executive branch. "Executive branch disputes of a legal nature are properly resolved by the President or his or her delegate..." (EPA 1990a). In view of the above, and for the purpose of this manual, the risk assessor should provide assistance to the USACE's project manager (PM), USACE's technical manager (TM), risk manager, and the USACE customer so that an FFA or IAG can be

successfully negotiated to provide a framework for risk management decision-making and to initiate actions to protect human health and the environment where these actions are needed. The risk assessor and the HTRW project team may consider the following areas for assistance to be provided to the USACE customer concerning the FFA negotiation: these areas have been identified in the DoD-EPA Model IAG Language (EPA 1989d):

1.7.1 Basis for Interim Remedial Action (IRA) Alternatives

For purposes of this guidance, IRA may be interpreted as interim corrective measure under RCRA or removal action under CERCLA. One purpose of the FFA is to identify IRA alternatives which are appropriate at the site prior to the implementation of final remedial action(s). To identify such alternatives, the exposure area (study area or the area of ecological concern), the exposure pathways which contribute to the principal threat at the site, and the receptors/resources must also be identified. For the purpose of the FFA, a statement may be entered which indicates the basis for identifying IRA alternatives. This statement should address the following:

- The approach for conducting a screening risk analysis of the exposure units (EUs) (EPA 1991c), SWMUs, or the AOCs.
- The evaluation method for the risk assessment/ analysis results (qualitative or quantitative).
- Risk management decision-making considerations (Chapter 9) for identifying and/or selecting the IRA alternatives.

1.7.2 Requirements for RI/RFI and FS/CMS

Another purpose of the FFA is to provide a framework for investigating, assessing the impact, and evaluating remedial options to protect public health and the environment. Such a framework, consistent with the NCP and the RI/FS guidance (EPA 1988a), may be modified and formally incorporated in the FFA to meet the site-specific and project requirements. Statements or languages or addenda to the FFA may be prepared by the risk assessor and the project team to serve as a basis for determining the extent of data collection, data evaluation, assessment of baseline risk, and evaluation of remedial alternatives. The HTRW data quality design process (USACE 1995b) and associated DQOs should be identified as the framework for determining data needs, data use, and data quality. The point of departure for no-further action and/or monitoring only based on acceptable risk should be identified in the FFA (EPA 1991d). The statement should indicate the phased approach recommended by this manual and other inputs from the expert ecologist, risk assessor(s), or advisory panels (e.g., BTAG/ETAG; Restoration Advisory Boards/Technical Review Committees [RABs/ TRCs]), including criteria used for assessment of uncertainties.

1.7.3 Expedited Cleanup Process

Both DoD and EPA are in agreement that early action or accelerated cleanup may be needed to stabilize the site and to facilitate implementation of the final remedies. However, the basis for such action is not well defined, except that the actions are intended to control contaminant migration, to reduce exposure, and to accelerate response. In addition to time-critical and emergency response actions where safety and acute hazards are involved, the risk assessor and the project team can provide valuable input to the USACE customer and risk manager for such expedited actions. This can be rather quickly accomplished by comparing the measured media concentrations with available human health and ecological risk-based protective criteria. This may be useful for relatively straightforward sites, such as drum removal, product removal, and containment. For response actions at a complex site, a baseline ERA may be more appropriate, however, and expedited cleanup would not be done. All decision criteria for eliciting response actions to protect environmental components should be well thought out, reasonable, and consistent with current EPA guidance.

1.7.4 Units Excluded from the Agreement

RCRA and CERCLA integration issues should be addressed in the FFA in unambiguous terms. This is particularly true for sites of which the state agency is also an interested party or natural resource trustee in the agreement. Some state agencies have their own risk assessment policies and guidances, and risk management decision-making criteria which may vary substantially from those of EPA (EPA's ERA procedures under RCRA and CERCLA are judged to be substantially equivalent at this time). The risk assessor should review state policies, guidance, and requirements, and identify any critical risk assessment/risk management issues for the PM, TM, and the customer for resolution. These issues should be addressed and resolved in the FFA negotiations. If not successful, separate FFAs may be needed to address RCRA and CERCLA units within the facility. The USACE and customer's legal counsels should be contacted for briefing on these issues early in the process.

Chapter 2
Ecological Risk Assessment Scoping Considerations

2.1 Introduction

This chapter introduces the conceptual and technical objectives for scoping an ERA and the elements that should be included in an ERA. The methodology for conducting the ERA is presented in greater detail in the following chapters. Chapters 2 through 8 are intended as a guide for enabling a risk assessor and risk manager to critically scope and evaluate ERAs, as well as appraise their quality for supporting potential site remedial responses at his or her site. These chapters present important components of the risk assessment, highlighting where planning and professional judgment are needed. They are not intended to present step-by-step instructions. Adequate guidance for preparing an ERA is provided in other resources as referenced throughout this manual.

The ERA is an integral component of the PA/SI, RFA, RI/FS, RFI/CMS, and emergency response processes. It serves multiple roles regarding the need for action at a site:

- The ERA provides an evaluation of the potential ecological risks under baseline (i.e., no action) conditions.
- The ERA helps to determine the need for remedial action at the site.
- The ERA provides a basis for determining remediation goals for chemicals in site media.
- The ERA can be used as a basis for comparing different remedial alternatives.
- The ERA provides a means for assessing potential ecological risks and for allowing comparison of potential ecological risks between sites.

The ERA is one component of overall site investigation and remedial activities. It should be developed with a recognition of how it is supported by preceding and concurrent components of site activities, such as sampling and analysis and the human health risk assessment effort, and how it supports and shapes the following components, such as remedial design. Although the ERA is performed to achieve several specific objectives (describing current and future ecological risks), it needs to be coordinated with other site activities (e.g., human health risk assessment) and needs to be responsive to other general site concerns (e.g., restoration, mitigation, litigation) and the resources (cost and schedule to be met) available.

Risk assessments have different applications in different regulatory programs.[1] The application of risk assessment is discussed in the following phases of site activity:

- PA/SI and RFA.
- RI and RFI.
- FS and CMS activities, including development of remediation levels and comparative risk assessments associated with selected remedial options followed by the evaluation of short-term risks associated with the implementation of the selected remedial option.
- RD/RA and CMI activities, including potential need to further evaluate short-term risks for the purpose of designing/implementing control measures.
- Assessment of residual risk after implementation of the selected remedial option.

Risk assessments developed for each of these activities will have slightly different scope or level-of-effort requirements. However, the technical basis for the risk assessment is essentially the same.

EPA's *Framework* (EPA 1992a) and *Risk Assessment Guidance for Superfund, Volume II (RAGS II),* (EPA 1989a) provide the general guiding principles and structure for the conduct of an ERA and the format of this manual. Forthcoming guidance from EPA Headquarters, Environmental Response Team (ERT), is expected to provide further details on an eight-step process for designing and conducting ERAs based on the *Framework* (M. Sprenger, EPA 1995c). Additionally, USAERDEC's (1994) *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* presents a similar framework

[1] Performance of an EBS under the BRAC program is not addressed in this guidance. However, the general concepts, particularly those for the Tier I ERA, are applicable to this program to meet the objectives of the Community Environmental Response and Facilitation Act (CERFA).

approach and a three-tier investigative process used to further enhance an understanding of the ERA requirements under CERCLA.

The framework for ERAs as presented in these references is conceptually similar to the approach used for human health, but is distinctive in its emphasis in three areas. First, the ERA can consider effects beyond those individuals of a single species and may examine a population, community, or ecosystem. Second, no single set of ecological values to be protected can generally be applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Finally, in addition to chemical-induced toxic stresses, ERAs may consider nonchemical-induced stresses (e.g., loss of habitat).

2.2 Scoping Considerations

The consistent standardized approach presented in these guidance documents was devised to ensure consistent treatment among sites. For scoping purposes, it should be noted that most ERAs are highly site-specific and often require unique investigative plans and actions. Numerous other resource materials, guidance documents, bulletins, memoranda, technical manuals, and books that address the general ERA approach and scoping of site-specific data needs are available from EPA, other regulatory agencies, and scientific sources. A number of these resources are referenced in Appendix B. A copy of the Framework (EPA 1992a) is provided in Appendix C. The following chapters provide the USACE risk manager with more detailed guidance information on the ERA process, along with "how to" and "where to find" knowledge for evaluating the scope, design, and conduct of a site-specific ERA.

2.2.1 Objectives of the Ecological Risk Assessment

The goat of the ERA is to provide the necessary information to assist risk managers in making informed decisions. The specific objectives of the ERA are: (1) to identify and characterize the current and potential future threats to the environment from a hazardous substance release; and (2) to establish remedial action objectives that will protect those ecological receptors at risk, if appropriate. The ERA provides important risk management input at various project phases, identifying ecological species or resources to be protected, as well as limitations and uncertainty.

The ERA should provide an objective, technical evaluation of the potential ecological impacts posed by a site., with the risk characterization clearly presented and separate from any risk management considerations. Although risk assessment and risk management are separate activities, the risk assessor and risk manager need to work together at various stages throughout the project to define decision data needs. In the ERA, the risk assessor needs to present scientific information in a clear, concise, and unbiased manner without considering how the scientific analysis might influence the regulatory or site-specific decision. The risk assessor is charged with:

- Generating a credible, objective, realistic, and scientifically balanced analysis.
- Presenting information on the problem, effects, exposure, and risk,
- Explaining confidence in each assessment by clearly delineating strengths, uncertainties, and assumptions, along with impacts of these factors (EPA 1995a).

The risk assessor does not make decisions on the acceptability of any risk level for protecting the environment or selecting procedures for reducing risk. The ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

2.2.2 Definition of Ecological Risk Assessment

According to EPA's *Framework* (EPA 1992a). an ERA is defined as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors. Stressor is defined by EPA as any physical, chemical, or biological entity that can induce an adverse ecological response. In the Superfund program, an ERA entails the qualitative and/or quantitative appraisal of the actual or potential impacts of a hazardous waste site on plants and animals other than humans or domesticated species. Substances designated as hazardous under CERCLA (see 40 CFR 302.4) are the stressors of concern. These definitions recognize that a risk does not exist unless: (1) the stressor has an inherent ability to cause adverse effects, and (2) it co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s).

No consensus definitions exist for many of the terms used in an ERA. Definitions herein are generally consistent with those used in the *Framework* (EPA 1992a) and *RAGS II* (EPA 1989a).

2.2.3 Planning for an ERA

Planning and problem identification are critical to the success of the ERA and its usefulness with respect to remediation planning. To ensure that the scope. of the ERA is sufficient for making risk management decisions, the risk assessor must always be mindful of the question, "Do the data and ERA approach support risk management decision-making?"

Planning for an ERA should be conducted concurrently with that for a human health assessment in that these two efforts often have similar data needs. ERA data needs are generally similar to those for human health risk assessments in the initial contamination characterization stages. Data needs for the ERA, however, eventually focus on developing remedial alternatives that are protective of ecosystem components, while the human health risk assessment focuses on developing remedial alternatives that are protective of a single species, humans.

Coordinated planning efforts for the ecological and human health risk assessment efforts, particularly where there is to be an expedited cleanup, should include consideration of the following:

- Overlaps in information needs with regard to human and ecological food chain issues.
- Benefits of the cleanup and the effectiveness of presumptive remedies.
- Ecological impacts from removal or remedial activities designed to protect human health.
- Identification of hot spots that may impact both human health and ecological receptors.
- Identification of the key assumptions and criteria common to the human health and eco-risk risk assessments that may drive cleanup decisions and focus the decision-making process.
- Early actions which may be taken at sites (i.e., OUs, CAMUs) that could quickly and at a relative lower cost reduce both ecological and human health risk.
- Identification of areas of greatest concern that may be addressed as discrete tasks in the ROD, thereby allowing priority to be given to those (removal/remedial) actions that achieve the greatest protection of the environment and human health for the capital (dollars) spent.
- Activities common to both the ecological and human health risk efforts that support DoD responsibilities as a Natural Resource Trustee or help coordinate between multiple Natural Resource Trustees where jurisdictions or responsibilities overlap.

ERAs employ a systematic planning format and process to ensure production of consistent and technically defensible ERAs. The ERA format and process, as described in the Framework, is designed to be flexible. Widely applicable regulatory protocols for formal site-specific ERAs are currently not available (in contrast to the approach used for human health). The flexible ERA process provides for coordination with the human health assessment in the chemical sampling program, determination of extent and degree of contamination, characterization of site risk. and the overall site management decision process.

In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, regulatory programs driving the HTRW project execution and the associated project decision statements (PDs),[2] the study elements for the relevant project phase, and the type of ERA needed based on the study elements. The concept of technical project planning is fully explained in the USACE's (1995b) Technical Project Planning Guidance for HTRW Data Quality Design, which emphasizes the need for the data users (e.g., the risk assessor) to identify minimum data requirements for the tasks to be performed.[3] The concept of "minimum requirements" for

---

[2] PDs represent specific planning objectives of HTRW site investigations and evaluations. Selected PDs become the principal focus of the data quality design efforts (USACE 1995b).

[3] The HTRW technical project planning is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options. Throughout the process, USACE HTRW personnel of various disciplines and responsibilities (some of whom may assume multiple responsibilities) work closely together to identify data needs, develop data collection strategy, and propose data collection options for the customer. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all phases of the project life cycle.

the ERA is important in that it identifies certain minimum requirements for data collection activities preceding the ERA to ensure that critical data gaps or factors are addressed. Examples of minimum requirements for a risk assessment are presented in Exhibit 1.

The approaches and contents of the anticipated ERA should be explained or discussed in the project planning stage in unambiguous terms. An iterative, tiered approach to the risk assessment, beginning with screening techniques, is used to determine if a more comprehensive assessment is necessary. The nature of the risk assessment depends on available information, the regulatory application of the risk information, and the resources available to perform the ERA. Informed use of reliable scientific information from many different sources is the central feature of the ERA process (EPA 1995a,d). The project planning process should produce an outline for a site-specific ERA that is credible, objective, realistic, and scientifically balanced. Since the ERA is conducted in an iterative, tiered approach, a decision diagram similar to that presented in Figures 2-1 and 2-2[4] should be presented for discussion.

Throughout the planning discussions, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "'real world" situation. Biological sampling programs often entail scheduling constraints, e.g., surveys for endangered speties (e.g., an orchid) should be conducted in the appropriate season (e.g., June, not December). When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed. The risk assessor should also explain the minimum data quality considered to be acceptable, how nondetects will be treated, and how medium-specific data will be evaluated or compiled to derive or model the exposure point concentration in the risk assessment[5]

The technical requirements of the ERA should be considered early in the HTRW process to ensure that appropriate information is gathered. It is important that the ecological risk assessor be involved in the early planning stages of field investigations, including ECSM develop ment, identification of site media, sampling plan design, data validation, compilation, and interpretation. This will help ensure that the best possible and most relevant data are available for use in the ERA. Coordination with an agency (EPA or DoD [USAEC]) BTAG/ETAG coordinator will also help ensure conduct of an effective and acceptable ERA.

The ERA should be developed, to some extent, with its end uses in mind. Early interaction with risk managers and remedial designers is needed to obtain information on the risk management options likely to be considered if remedial action is required. This is not to infer that the ERA should be tailored to specific remedial options, for that would compromise the objective nature of the assessment. However, if the risk manager or remedial designer needs to know certain factors (for example, how thick must the cap be to prevent onsite burrowing animals from being at risk), the risk assessor should provide the basis that will allow him or her to answer this question.

In the risk planning process and on Superfund sites in particular, it is also important for the risk assessor, risk managers, and decision-makers to coordinate with natural resource trustees (e.g., DoD, the State, NOAA[6] USFWS, USFS, and BLM) at the earliest possible stage. In this

[4] Details presented on the tiered ERA process in these figures are elaborated upon in succeeding chapters. See Section 2.4 for an introduction to USACE's four-tiered EPA approach.

[5] For example, if the RI data are skewed, it may be necessary to address site risk by evaluating hot spots separately. The risk assessor may wish to indicate this in the Work Plan, in order to characterize hot spot areas without delaying the assessment of risks for the non-hot-spot areas.

[6] NOAA's Coastal Resource Coordination Branch (CRCB) works with EPA through all phases of the formal remedial process at Superfund waste sites. The CRC Branch acts for the Dept. of Commerce as trustee for natural resources such as anadromous and marine fish. Coastal Resource Coordinators (CRCs) and an advisory staff of environmental, marine, and fisheries biologists provide technical support and expertise to EPA, DoD, and other agencies during response and cleanup at coastal waste sites. The CRCs and supporting staff recommend appropriate environmental sampling, coordinate with other natural resource trustee agencies to build consensus on natural resource issues, and recommend appropriate cleanup levels. The CRCB works with EPA to gain cost-effective remedies that minimize residual resource injury without resorting to litigation. CRCs are in most EPA regions (not in Regions 7 and 8; coming soon to Region 5). See Appendix B for additional information on NOAA programs.

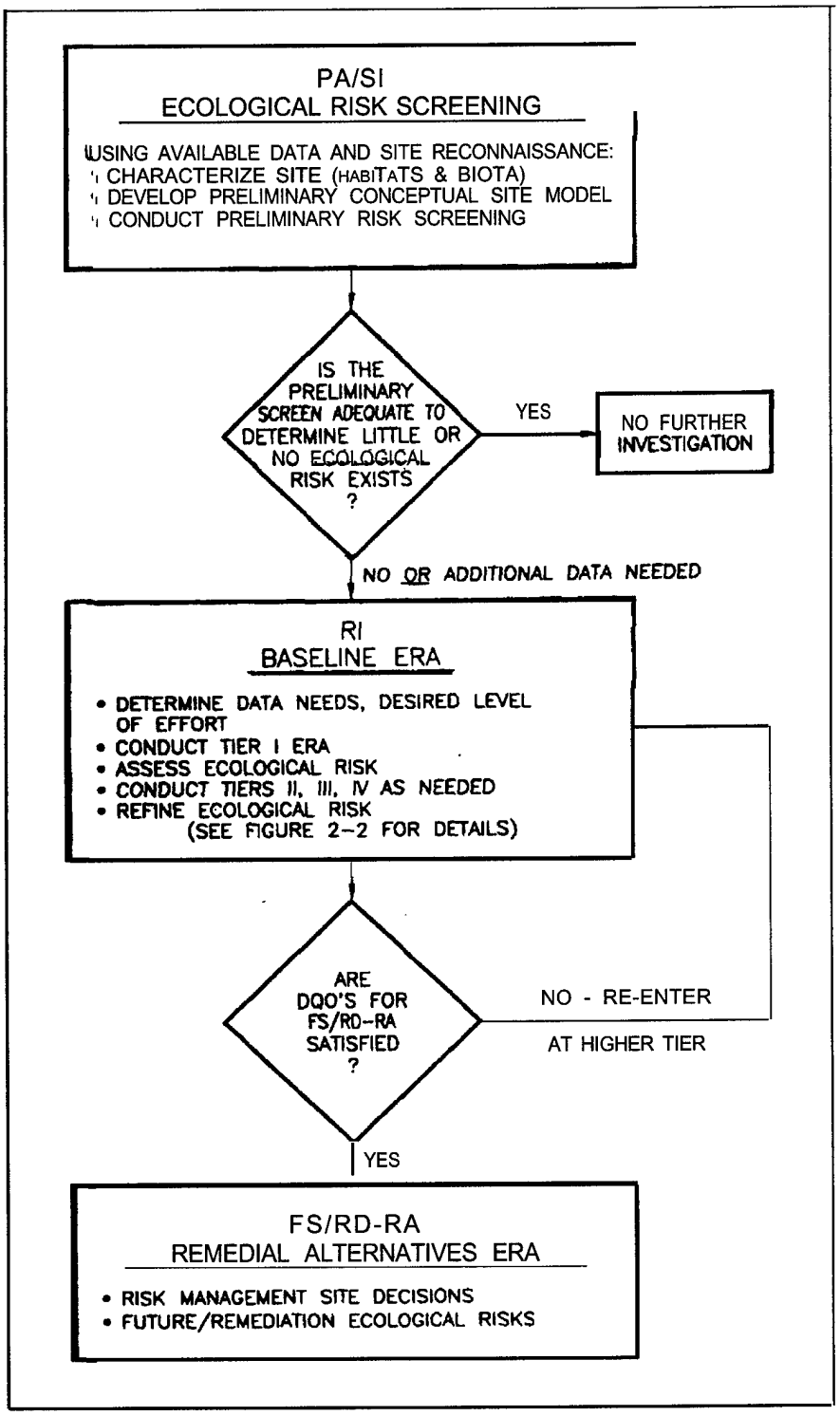


Figure 2-1. ERA flow chart

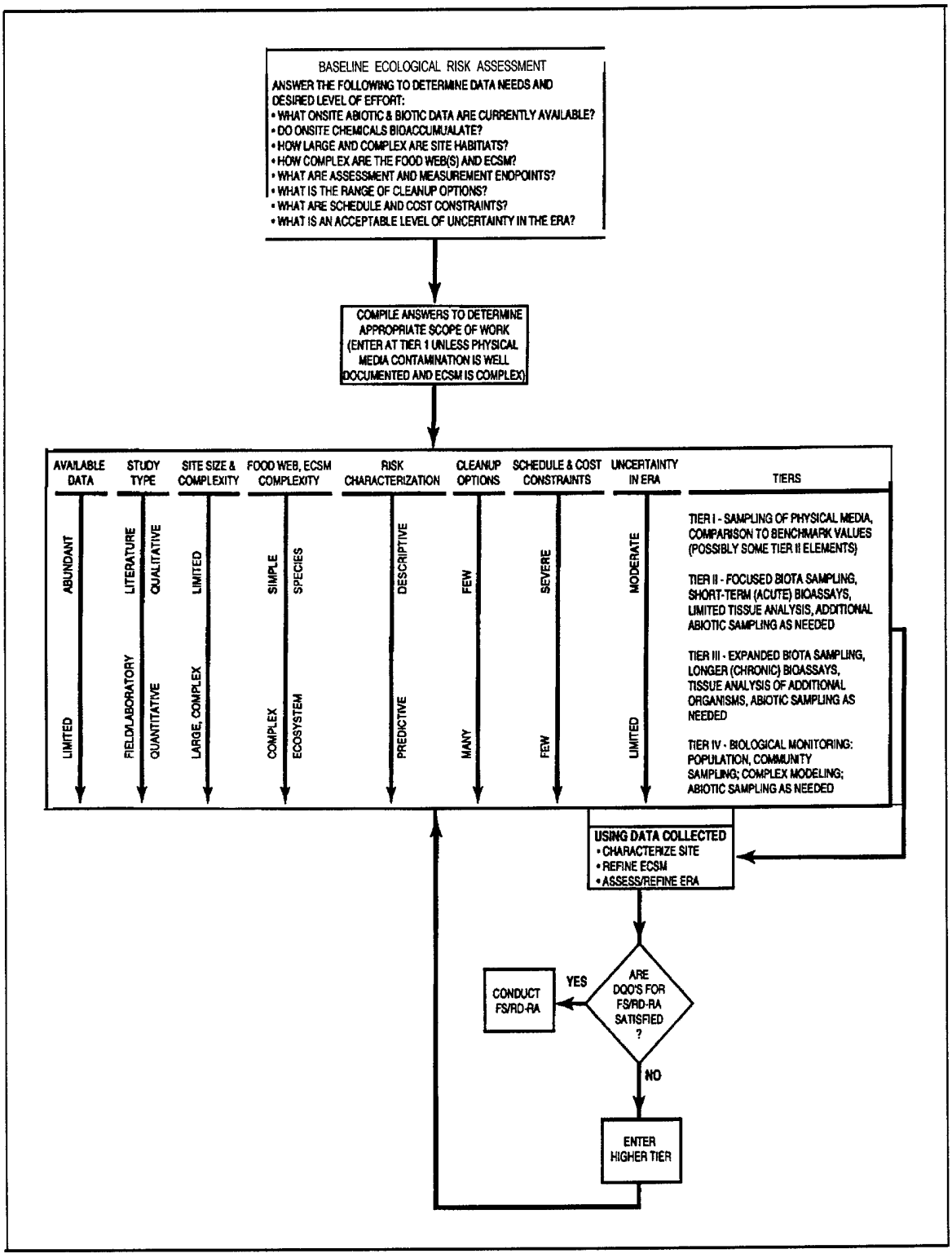


Figure 2-2. Baseline ERA flow chart

way, the trustee can be assured that potential environmental concerns are addressed and conclusion of action may be expedited (EPA 1989a). Coordination with natural resource trustee agencies such as NOAA provides for the exchange of ideas and issues to ensure the technical adequacy of the RI/FS, to ensure the protectiveness of the selected remedy for trust resources, and to provide for proper restoration and mitigation for injured resources. Coordination also allows DoD access to the trustees' specific skills, information, and experience in ERAs. This interaction may occur through a variety of informal and formal forums, including but not limited to: preliminary scoping and drafting of work plans, review of final work plans and subsequent data, technical review committees, PM/TM meetings, and public information meetings.

2.2.4 HTRW Policy and Technical Project Planning

The ERA process presented herein is consistent with DoD and EPA policy and guidance. Recent EPA (1995d) risk characterization guidance reaffirms the principles and guidance found in earlier EPA (1992g) policy, Guidance on Risk Characterization for Risk Managers and Risk Assessors. EPA's (1995a,d) risk characterization policy establishes the core values of clarity, transparency, reasonableness, and consistency in both ecological and human health risk assessments across Agency programs. Adherence to this policy is intended to:

- Ensure that risks are characterized fully, openly, and clearly.
- Promote full disclosure of scientific analyses, uncertainties, assumptions, science policies, and the rationale which underlie decisions as they are made throughout the risk assessment and risk management process.
- Improve the understanding of ERAs, to lead to more informed decisions, and to heighten the credibility of both the risk assessment and risk management decisions.

Risk management is an important aspect of USACE's HTRW program. To ensure the utility of the ERA in meeting risk management needs, the HTRW Technical Project Planning process laid out in EM 200-1-2 (USACE 1995b) should be followed. In accordance with this planning process, the USACE PM and/or TM provides the leadership to define a site strategy and to effectively communicate this strategy.

Risk assessment is based on a series of questions about scientific information that is relevant to the estimation of risk. Each question calls for analysis and interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem, and scientific conclusions regarding the questions presented. The HTRW planning process is used to focus on data needs and to design quality data collection options. The HTRW planning process also encourages early refinements of the data collection options as a means of identifying cost-effective options for selection. By emphasizing the process, it is expected that the ERA will be useful as a site-decision-making tool.

2.2.5 The HTRW Technical Project Planning Process

USACE recognizes the need for cost-effective and efficient site investigation/response actions. The HTRW Engineer Manual 200-1-2, *Technical Project Planning Guidance for HTRW Data Quality Design* (USACE 1995b) provides guidance on data collection programs and defines DQOs for HTRW sites. The HTRW technical project planning process is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options.

DQOs define the project's data needs, data use, number of samples desired, the associated quality assurance requirements (e.g., detection limits, blanks, split and duplicate samples, etc.), and level of confidence or acceptable data uncertainty for the requisite data. DQOs are generated at the final phase (Phase IV) of the HTRW data quality design process after the customer has selected the preferred data collection program (ER 1110-1-263, USACE 1995c). The process includes evaluation of previously collected data and assessment of need for additional data to support the study elements for the current or subsequent phases of the project. 'Ibis coordinated project planning effort is designed to satisfy the customer goals, applicable regulatory requirements, and minimum technical data requirements for performing a site-specific ERA.

Throughout the process, USACE HTRW personnel of various disciplines and responsibilities work closely together to identify data needs, develop data collection strategy, and propose data collection options. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all

phases of the project life cycle. The DQO development process is considered to be a total quality management (TQM) tool (EPA 1989e). Incorporating the HTRW data quality design and technical project planning process is key to ensuring successful planning and performance of the ERA.

Three basic questions related to the use of the HTRW technical project planning approach are:

- What decisions are the data intended to resolve? What are the primary and secondary regulatory programs that require data input? What are the customer's goals and concept of site closeout? Where is the project phase under such program(s)? What are the PDs for the project phase?

- Why does the customer (or the data user) need a specific type and quality of data? What are the study elements for the project phase? What are the minimum data requirements for the study elements? What am the data quality requirements to satisfy PDs? (For example, to eliminate sites early in the project phase based on the lack of ecological resources of concern, the study element could be an environmental survey and assessment to identify the presence or lack [unrelated to contamination] of ecological resources of concern. The data quality associated with the survey and assessment will need to be specified. Involved parties would also have to agree on the finding that ecological resources of concern [potential assessment endpoints] are absent.)

- How will data be used to defend site decisions? How will the results of the study be used to satisfy PDs? What are the data collection options and anticipated removal/remedial options, if applicable? What is the customer's preference or choice for the options? How should the selected option(s) be implemented? (If sensitive receptors are identified at a site, the customer may choose to further evaluate the impact by collecting data to support a baseline ERA. Alternatively, the customer may chose to negotiate with the regulatory agencies on various interim measures or remedial actions to mitigate the release or rehabilitate the site).

Phases I through IV (described below) of the HTRW technical project planning elements address the above questions methodically and should be incorporated or used in the entire HTRW project life cycle. Using this technical project planning process, the risk assessor will be able to define minimum information requirements for risk evaluations in support of site decisions. Further explanation of the HTRW data quality design approach as it relates to the conduct of the ERA is provided in Appendix D. The utilization of key information identified in the ERA for risk management decision-making is described in Chapter 9.

2.2.5.1 Phase I - Develop Project Strategy

This phase of the project planning process involves identifying site decision requirements and developing an approach to address these requirements. Site strategy is broadly defined in the beginning of a project at this stage. As the project progresses into subsequent phases, the strategy is refined based on an improved understanding of the site. The risk assessor is crucial to the development of appropriate site strategy in this phase and the identification of data needs/quality to support risk management decisions. In this planning phase, site conditions am reviewed qualitatively, and a preliminary ECSM is developed to help define the study elements for the current and subsequent project planning phases. In terms of project execution, key inputs required for decision-making can be more readily defined after site-specific conditions are generally understood.

2.2.5.2 Phase II - Identify Potential Data Needs to Support Decisions

This phase of the project planning process focuses on identifying data needs and minimum data quality requirements to support site decisions identified in the PDs. Data users identify potential data needs and their respective proposed quality assurance/quality control requirements based on site background, regulatory information, and the customer's goal. At this phase, the compliance specialist, remedy-design engineer, and responsibility-legal data users, who have specific data needs, present their data requirements along with the data needs identified by the risk assessor. The objective is to scope out data needs and quality requirements by ah project team members. Data requirements are documented so that the data implementors, chemists, geologists, and/or statisticians may recommend potential optimum sampling design and data collection options for selection and implementation.

At most sites it is unusual for massive, adverse, ecological effects impacting sensitive species or valued resources (assessment endpoints) to be readily observed in a field survey. Consequently, multiple data or measurement

endpoints are needed to infer or link the collected data with the assessment endpoints. The likelihood or tendency to overscope data needs at this project planning phase is high, if an iterative approach is not followed. The danger of falling into a trap of endless research studies without added benefits can readily occur if the risk assessor attempts to address all uncertainties in a single study.

Contaminants found on many CERCLA/RCRA sites are commonly localized to small areas. In these cases, perturbations on the overall structure and function of valued (societal and ecological) populations (excluding threatened and endangered species), communities, or ecosystems are often found to be negligible. Depending on the specific site conditions (or presence of protected receptors), simple screening methods and limited field studies or bioassays (e.g., Tier I or Tier II approach as described in Chapters 4 and 5, respectively), are frequently adequate for risk management decision-making.

To select the proper risk assessment approach, given time and resource constraints, it is important that the risk assessor has the proper training and experience to scope and manage the ERA. To the extent feasible, the experience and skill of expert ecologist(s) and advisory groups (BTAG/ETAG) should be leveraged when identifying the data needs for the ERA. Data needs consistent with customer's goals and concept of site closeout, time/budget, site and project strategy, PDs, and the project study element requirements are documented as part of the Phase II requirements. This information in turn is communicated to the data implementors for developing sampling strategies and data collection options under Phase III.

2.2.5.3 Phase III - Identify Data Collection Options

This phase of the technical project planning process incorporates previously identified data needs and project constraints in designing a data acquisition approach. Various sampling approaches can be used, ranging from purposive (judgmental or biased) to representative sampling methods. Data may also be obtained from single-step to multi-step abiotic (media) investigations, from single species and microcosm (multitrophic levels) laboratory toxicity tests to mesocosm, sentinel and field surveys, or to long-term (multiseasons and multiyear) modeling and monitoring studies of ecological community function and reference areas to satisfy data needs critical for the site decisions.

This phase of project planning also involves identifying the optimum sampling/data collection scheme so as to minimize mobilization, field sampling, and demobilization efforts and costs. The objective of Phase III is to identify options (preferably two or three options, out of which one is an optimum option) for presentation in Phase IV.

2.2.5.4 Phase IV - Select Data Collection Options and Assign DQOs

This is the most important phase of the project planning/ execution process, because this is where data collection options are selected. To properly execute Phase IV, the proposed options should be clearly explained and characterized. The discussion should include data uncertainties, cost/benefits, schedule, and other constraints. Based on feedback from the customer or decision-maker, the project team may have to refine the preferred option(s). Prior to the presentation of options, it is recommended that the PM or TM review the options to determine if they are consistent with site strategy and meet the requirements of the PDs.

The project team critically reviews the output from Phase I through Phase III of the project planning process to recommend an array of options. Specifically, the project team reviews the army of data collection options and reexamines the PDs, data needs (including critical samples, i.e., samples necessary for the site decision at that project execution phase) and their quality assurance requirements, budget/tie constraints, the customer's goals, and regulatory/compliance requirements. The team reexamines whether the options meet the project strategy and whether the options are cost-effective in terms of meeting minimum data requirements of the data users and the site decision-makers for the current phase. as well as subsequent phases of the project.

Because ERAs typically have limited budget and time for completion, data requested for the ERA should be action-oriented, i.e., they should assist the customer to make informed decisions. It is critical that sufficient data are collected to address uncertainties associated with the ERA. Although such uncertainties can often be addressed via long-term research projects or studies, these are generally not appropriate under RCRA and CERCLA. The purpose of an ERA is not to prove an ecological effect or accurately predict such effect, but to reasonably determine the degree to which hazardous constituents or wastes have impacted or could impact the structure. function. and dynamics of the ecosystems (i.e., biological diversity,

functional integrity, energy and nutrient dynamics). If the impact is judged to be significant, further action will be warranted.

The products of this phase of the project planning process are the Statement of Work (SOW) for USACE work acquisition (either internal or the architectural-engineering [A-E] contractor), a detailed cost estimate for the selected option, and DQOs for the data collection program. The DQOs explain the objectives of the data gathering activity, the data type/location, data collection and analytical methods, rationale for requiring certain data quantity and quality, and how the data are to be used in making site decisions. If the acquisition strategy in Phase I technical project planning was to seek assistance of an A-E contractor, the DQOs and the appropriate information from Phases I through III will also be provided to the contractor to develop the Sampling and Analysis Plan (SAP) (synonymous with Chemical Data Acquisition Plan. USACE 1995a,b), in order to meet the goals and objectives of the next executable phase of the project life cycle. Caution should be taken at this point about the integration and coordination between the human health assessment and ERA as to how they influence DQOs. RAs may require lower media-specific detection limits than human health assessments for certain COECs and vice versa. The ultimate DQOs should be the lower of either for dual purpose samples, or the appropriate concentration for specific purpose samples.

Depending on the level of expertise and familiarity of the contractor with the project, the USACE HTRW PM may elect to allow the contractor to assume some responsibilities to complete Phases II through IV, with input from USACE. In terms of technical project planning for ERAs, it is critical that the contractors are trained and understand the Corps ERA approach, the customer's objectives and site strategy, and have the required experience.

The Phase IV project planning process involves the selection and documentation of the data collection program in support of an ERA or risk analysis. Such documentation will provide a historical knowledge which justifies and guides the data review and data use.

2.2.6 Approaches to the Conduct of an ERA

The approach and level of effort for an ERA are based on DQOs developed under the HTRW technical project planning process. DQOs address data quality and quantity requirements and data use. DQOs am integral to the design and conduct of cost-effective and efficient ERAs under current and future land-use scenarios.[7] While the overall framework for the conduct of the risk assessment should remain consistent with the Framework paradigm, the risk assessor may apply a variety of approaches and classification schemes in the conduct of the ERA. Two distinct approaches are generally seen in ERAS: the criteria-based approach and the ecological effects-based approach.

A preliminary ERA screen is generally based on the criteria or chemical concentration-based approach. Chemical criteria, such as state and Federal ambient water quality criteria (AWQC) or naturally occurring background concentrations, are routinely screened against in the initial investigation stage of an ERA. Ecotoxicological risk-based screening concentrations (RBCs), similar to human health RBCs, are being developed in some EPA regions. These chemical screening concentrations represent conservative values that are designed to be protective of specific ecosystems (aquatic, terrestrial, wetland) and can serve as a technical basis for the development of site-specific cleanup objectives. Numeric screening concentrations, however, are not available for a great many chemical contaminants.

The ecological effects-based approach is more commonly applied in the baseline ERA. This approach is based on the detailed evaluation of site-specific conditions using toxicity tests or actual biological measurements. This approach is commonly applied to aquatic ecosystems, where standardized American Society for Testing and

[7] For example, if the intended use of the site after site closeout is a park/recreation area, the data to be collected to support the ERA will be quite different from the future land use of an industrial park. The former may involve identifying the potential ecological receptors of concern (based on a reference park/recreational area), availability of food sources, and assessing the potential effects of the potential COECs, under the no-further-action scenario. The data needs and DQOs for the latter land use may only include collecting data to ensure that the current site condition and its conversion to an industrial park will not impact potential ecological receptors in the vicinity of the site, including those in surface water bodies. EPA's land use guidance, *Land Use in CERCLA Remedy Selection Process* (EPA 1995e) and other land use information should be reviewed as part of the HTRW technical planning process.

Materials (ASTM) test methods may be used. This causal evidence approach allows for the identification of biological or ecological impacts without specific accountability for the chemical causative factors and is not constrained by the limitations of chemical analytical techniques. Chemical concentration data are used primarily to establish general accordance. As proof of causality is not a requirement for the ERA, the evaluation of causal evidence is used co augment the risk assessment. Criteria for evaluating causal associations have been suggested by Hill (1965) and are provided in EPA's (1992a) *Framework.*

Both of these approaches are part of the overall strategy of the Framework approach for establishing site-specific remediation objectives (see Section 2.3). The following chapters are directed more toward the former approach in their presentation of the quotient methodology and discussion of risk-based screening concentrations. The toxicity test approach is described in much greater detail in two recent documents: *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994) and *Methodology for Aquatic Ecological Risk Assessment* (WERF 1994).

ERAS also entail the use of various classification schemes such as: qualitative versus quantitative, predictive versus retrospective, empirical versus theoretical, and top-down versus bottom-up methods. These schemes have been described in publications by Parkhurst et al. (1990), Norton et al. (1988). and Pastorok and Sampson (1990) 'and in Environment Canada's (1994) *Framework for ERAS.* Use of a particular classification scheme rests on site-specific objectives and, to a great degree, the knowledge and experience of the risk assessor.

2.2.7 Establishing the Level of Effort

The preliminary level of effort and nature of the ERA are directly related to the PDs that need to be addressed. Boundaries need to be set early in the scoping process, since the amount of information that could be. incorporated into an ERA is potentially limitless. Although often predetermined to a large extent by schedule and budget constraints, these boundaries should be tied to the objectives of the preliminary assessment and the site-specific nature of the potential risk.

Before initiating the ERA, project planning is generally conducted to help set priorities and establish budget constraints. Early project planning establishes the focus and complexity of the ERA. Project planning includes a review of the available background material and discussions to define the scope and critical aspects of the ERA. Spatial boundaries such as the size of the site, extent of contamination, potential threats to onsite and nearby ecosystems, and important ecosystem components (e.g., fisheries) greatly determine the potential scope and design of the ERA. Any remediation or restoration plans for the site should be considered in the planning stage. Data deficiencies should also be recognized at this stage to the extent possible. Recognizing these planning elements and articulating specific objectives early in the planning stage will drive the design and focus of the subsequent ERA efforts. The methodology for conducting an ERA, as described in this manual, is based on a four-tiered approach. The four-tiered approach is introduced in Section 2.4 and presented in detail in Chapters 4 through 8.

2.3 Introduction to the ERA Process

This ERA process presented herein is based on EPA's *Framework* and its risk paradigm for ecological assessments. The framework consists of three major phases or parts: (1) problem formulation, (2) analysis, and (3) risk characterization. Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the risk assessment. Its end product is a conceptual model that identifies the environmental values to be protected (assessment endpoints), the data needed (measurement endpoints), and the analysis to be used. The analysis phase develops profiles of environmental exposure and ecological effects of the COECs on the receptors of concern. The exposure profile characterizes the ecosystem, in which the COECs may occur, as well as the biota that may be exposed. The exposure profile also describes the magnitude and spatial and temporal patterns of exposure. The ecological effects profile summarizes data (or in some cases, bioassessment results) on the effects of the COECs on the receptors of concern and relates them to the assessment and measurement endpoints. Risk characterization integrates the exposure and effects profiles. Risks can be estimated using a variety of techniques including comparing individual exposure and effects values, comparing the distribution of exposure and effects, or using simulation models. Risk can be expressed as a qualitative or quantitative estimate. depending on the available data.

Most ERAS include an initial risk screening assessment to provide an initial delineation of the problem and to help structure the baseline ERA should one be needed. The screening ERA is a streamlined version of the complete *Framework* process and is intended to allow a rapid determination by the risk assessor and risk manager if the site poses no or negligible risk. The basis of the screening level assessment is the ecological site characterization and

the comparison of site abiotic media concentrations with existing environmental criteria and guideline values (i.e., ARARs), such as Federal and state[8] AWQC: marine sediment effects levels (Long et al. 1995); freshwater sediment effects levels (Persaud, Jaugumagi, and Hayton 1992); or other readily available screening-level ecotoxicity values. The basis for applying the existing environmental criteria and guidelines draws on factors introduced later and presumes an understanding of the risk assessment methodology.

Environmental criteria such as Long et al.'s (1995) sediment criteria, EPA's (1993b) proposed sediment criteria, or EPA AWQC are not the same as remediation levels discussed in Chapter 8. In general, environmental screening criteria should be highly conservative and should not necessarily be applied as cleanup objectives at a site. The sediment criteria and AWQC may be used as a screening tool prior to the performance of an RI or RFI. Remedial levels are developed later from the site-specific baseline ERA and are tailored to site ecology as well as management objectives. The biological/ecological basis for each screening criterion should be carefully considered if used for more than screening, since it is entirely possible that such criteria could be overprotective or underprotective of the potentially exposed receptors, depending on site-specific biological, physical, and chemical characteristics.

A screening ERA may be performed for a PA/SI (RFA), or as the initial step in the RI (RFI) baseline ERA. In addition to environmental criteria, other factors that should be considered in the screening ERA include habitat suitability (e.g., absence of suitable habitat because location is an industrial area) and exposure pathways (e.g., absence of complete exposure pathways to ecological receptors). If the initial risk screen suggests the site cannot be eliminated based on environmental criteria or suitable habitat and exposure pathway considerations, project planning may occur to review the screening results and define the scope and critical aspects of performing a baseline ERA. Spatial boundaries such as the size of the impacted areas or potential threats to important ecosystem components (e.g., threatened and endangered species and their habitat) greatly determine the potential scope and design of the baseline ERA. Data deficiencies may be determined early on as part of the risk screen. Recognizing these planning elements and articulating specific objectives early in the risk screening stage will determine the need and drive the design and focus of the baseline ERA. The decision to continue beyond the preliminary ecological risk screen does not indicate that risk is unacceptable or that risk reduction is necessary, rather it indicates that a more focused evaluation and characterization of the risk and accompanying uncertainty is needed.

The baseline ERA is a process that combines data from biotic and abiotic media along with exposure and toxicity information to provide a determination of environmental risk. The methodology presented in this chapter for performing the baseline ERA has largely been developed by EPA for activities undertaken under CERCLA. This methodology is appropriate for ERAs performed as part of CERCLA RIs or RCRA RFIs. as well as many other situations. The two primary guidance documents that form the basis for the discussion on ERA methodology include:

- *Risk Assessment Guidance for Superfund - Volume II: Environmental Evaluation Manual (RAGS II).* Interim Final. (EPA 1989a).
- *Framework for Ecological Risk Assessment (Framework).* Risk Assessment Forum. (EPA 1992a).

Supporting Federal and state guidance documents, methods documents, and information sources are provided in Appendix B.

The baseline ERA provides an objective, technical evaluation of the potential ecological impacts posed by a site. The baseline ERA should be clear about the approaches, assumptions, limitations, and uncertainties in the evaluation to enable the risk assessor and manager to interpret the results and conclusions appropriately. The baseline ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

While the methodology for conducting the ERA is presented in detail in the following chapters, this manual is not intended to be a step-by-step instruction manual. Rather, it is intended to be a guide for scoping and critically evaluating the screening and baseline ERAs. Adequate guidance is provided in other resources for performing and preparing an ERA, and is referred to throughout the remainder of the manual. This and the following chapters discuss the important components of the screening and baseline ERAs, highlighting where up-front planning and professional judgment are needed. The

[8] Both state and Federal AWQC should be reviewed as state AWQC can be more stringent than the Federal criteria.

goal in providing the following detailed description of the baseline ERA process is to enable a risk manager to critically appraise the scope, conduct, and quality of an ERA for his or her site.

2.4 Introduction to the Four-Tiered Approach

A four-tiered approach is incorporated in the conduct of a baseline ERA and the evaluation of potential adverse effects on ecological receptors. The four tiers are:

- Tier I - Preliminary Ecological Risk Assessment: The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical-concentration based approach.

- Tier II - Focused Biological Evaluation and Sampling: The Tier II ERA is recommended where there is a need to reduce uncertainty or verify Tier I findings by using a biological effects-based, sampling approach.

- Tier III - Expanded Sampling Program: The Tier III ERA is recommended where longer term or more extensive biological or chemical sampling programs are needed to resolve issues presented by larger sites having complex ecosystems.

- Tier IV - Monitoring Program: The Tier IV ERA is reserved for the largest and most complex sites and is only appropriate where multiple year, biological monitoring or sampling programs are needed, and an ERA with the highest degree of certainty is required.

The tiered approach to the baseline ERA is composed of sequentially more sophisticated and complex evaluations. Therefore, scoping of the ERA for different tiers will require various data needs to be satisfied. Sequential evaluation, feedback, and flexibility allow for sound scientific judgments and efficient use of resources by minimizing unnecessary data collection, focusing major efforts, and optimizing benefits. Each tier has a similar three-part framework and builds upon knowledge. data, information, and decisions from the preceding tier, with each becoming progressively more focused. Although each tier is, in essence, a stand-alone evaluation, consistency and continuity are needed to keep the focus on assessment endpoints intact as the baseline ERA proceeds to higher tiers.

Within each tier, the baseline ERA, like the screening ERA, consists of the three major parts described in EPA's Framework:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

The tiered approach to the baseline ERA is an iterative process, with each subsequent tier including the same three parts, but building on information provided in the previous tier. Within each tier, new biological, toxicological, and abiotic chemical data are collected or evaluated. in order to revise and focus the ERA effort (see Figure 2-2). Also, within each higher tier, the data collection effort generally shifts from direct chemical analyses of abiotic media to short-term biotic sampling to longer term biotic sampling. The tiered approach is designed to address a series of questions regarding ecological conditions and effects at a site. Decisions are made in each tier as whether to proceed to the next tier and what specific sampling analyses should be conducted, based on the adequacy of data collected up to that point. While proceeding to the next tier may entail an expansion of time and effort, use of the iterative tiered approach provides a way to focus the ERA on specific decisions and DQOs throughout the process. The tiered approach offers an opportunity for decision-making at a variety of steps and thereby eliminates unnecessary testing and focuses resources on the important problems.

Tiering of a site-specific ERA is intended to provide a flexible, cost-effective management mechanism for the site investigation. While the baseline ERA process follows the simplified Framework structure, the actual level of effort within and between tiers may be both nonsequential and iterative. The order of actions taken depends on site status, RI/FS or RFI/CMS stage, amount and types of site information available, the necessity of multiple sampling events, and other factors. While the tiered approach is intended to maximize efficiency of data collection, there are cases where the tiered approach may require multiple field programs or time delays. In some cases, logistics and cost considerations outweigh the benefits of tiered testing. The scope of the effort and cost/benefit of applying the tiered approach are determined

through project planning, DQO evaluation, and through risk management decisions based in part on the results of the screening ERA.

Overall, the tiered approach is designed to ensure that all procedures to be performed are appropriate, necessary, and sufficient to characterize the nature and extent of effects to biota under the current and future land (or resource) use scenarios. To evaluate the relationship between contamination and ecological effects, the tiered approach requires iterative reevaluation of strategy objectives and data needs throughout the process, based upon the integration of three types of information:

- Chemical: Chemical analyses of appropriate media to establish the presence, concentrations, and variabilities of specific toxic compounds.
- Ecological: Ecological information to document potentially exposed ecosystems and populations (or threatened and endangered individuals): to characterize the condition of existing communities; and to observe whether any obvious adverse effects have occurred or are occurring.
- Toxicological: Toxicological and ecotoxicological information or testing to establish the link between adverse ecological effects and known contamination.

Without these three types of data, other potential causes of the observed effects on ecosystems unrelated to the presence of contamination, such as natural variability and human-imposed habitat alterations, cannot be eliminated. Use of the tiered approach is intended to maximize the efficiency of data collection in each of these three areas, using the information obtained at each tier to focus on the problem, and optimize the design of the next tier, if needed.

The four tiers and their interrelationship are shown on the flow charts in Figures 2-1 and 2-2. Figure 2-1 shows the overall relationship of the baseline ERA to the screening ERA and the Remedial Alternatives ERA (FS/RD-RA). Figure 2-2 shows the interrelationship of the four tiers within the baseline ERA. As shown in Figure 2-2, the number of tiers likely to be included in the baseline ERA depends on the PA/SI screening ERA results, specific project planning objectives and determination of data needs (see USACE's [1995b] HTRW Technical Project Planning document), and potential constraints such as schedule and cost, or cleanup options. Whether or not to proceed from the Tier I ERA to a focused biological field sampling program (Tier II), or an expanded biological sampling program (Tier III), or a multiple-year sampling program (Tier IV) will depend on how decision data needs are satisfied during the Tier I effort.

Chapter 3
Evaluating the Screening Ecological Risk Assessment

3.1 Introduction

The screening ERA follows general EPA guidance as presented in the Framework (EPA 1992a) and RAGS II (EPA 1989a). The screening ERA is a generalized, simplified assessment that is conducted by assuming conservative values for parameters where data are lacking. A screening ERA assessment may be performed as part of the PA/SI or RFA effort or as the initial Tier I effort during the CERCLA RI or RCRA RFI. The screening ERA consists of the following elements:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

3.2 Problem Formulation

Problem formulation begins with a compilation of readily available information on the environmental setting and potential contamination problem. EPA suggests use of their environmental checklist (EPA 1993a) in conjunction with a site visit by a qualified ecologist/biologist to help determine the level of effort needed to assess ecological risk at a particular site. Knowledge of the environmental setting and potential contaminant migration pathways allows for an early determination of the presence or absence of complete exposure routes and the potential for significant ecological impacts. State and Federal laws (e.g., CWA, ESA) designate certain types of receptors (endangered species) and environments (critical habitats, wetlands) that require special consideration during the risk assessment process or protection at the remediation stage. Knowledge of pertinent state and Federal laws pertaining to natural resources and sensitive environments at the site is a key element of the problem formulation step and the identification of assessment endpoints. Ecological information on potentially impacted environments and components can be derived from installation natural resource personnel, state natural heritage reports, and Federal agencies such as the USFWS.

3.2.1 Chemical Data Collection and Review

Appropriate data must be used for the screening level assessment to meet its objectives. Data available from PA/SI and RFA activities are usually limited in number but should be broad in scope of chemical analysis and in the number/type of abiotic media sampled.

Sampling should have been conducted in areas of suspected contamination and background areas to distinguish site contamination from background levels and to provide information on the "worst case." If sampling was not conducted in areas of suspected contamination, the screening ERA will not provide an adequately cautious assessment of potential risk. Similarly, if a broad chemical analysis was not performed, or if data are not available for all abiotic media of potential concern, the screening ERA will be limited and cannot be used to eliminate the site from further consideration,

The following are examples of minimum requirements for data applied to a PA/SI or an RFA screening level assessment:

- Chemical-specific analyses of appropriate abiotic media of potential concern (soil, sediments, surface water).
- Data of good quality according to the analytical methodology applied.

3.2.2 Ecological Conceptual Site Model

A preliminary ECSM may be developed during the problem formulation. The ECSM is a simplified, schematic, diagram of possible exposure pathways and the means by which contaminants are transported from the primary contaminant source(s) to ecological receptors. The exposure scenario(s) usually include consideration of sources, environmental transport, partitioning of the contaminants amongst various environmental media, potential chemical/biological transformation or speciation processes, and identification of potential routes of exposure (e.g., ingestion) for the ecological receptors. Because this is a screening effort and knowledge of site-specific ecological receptors may be lacking, the ECSM should be quite simplified, incorporating general categories (e.g., terrestrial or aquatic biota) in place of site-specific ecological receptors.

3.2.3 Problem Formulation Summary

A problem formulation summary typically includes the following:

- The environmental setting: contaminants expected, and maximum (or 95% upper confidence limit [VCL]) concentrations on a medium-by-medium basis.
- Contaminants and likely categories of ecological resources and receptors that could be affected.
- The complete exposure pathways that may exist within the impacted area.

Assessment and measurement endpoints are generally identified in the screening BRA. For the screening ERA, assessment endpoints include any likely adverse ecological effects on ecological resources of concern, for which exposure pathways are complete, as determined from the information listed above. Measurement endpoints are based on available toxicity values from the literature (i.e., toxicological endpoints). Through the exposure-response evaluation, exposure at or above levels at which adverse ecological effects might be expected are established from the contaminants and exposure pathways of concern.

3.3 Exposure and Effects Analysis

The analysis process consists of two interrelated efforts: exposure characterization and effects characterization.

3.3.1 Exposure Characterization

The two primary objectives of the exposure characterization are (1) identification of the important ecological receptor(s) or receptor group(s) in relation to the assessment endpoint(s), and (2) selection of appropriate exposure pathways and exposure point estimates. Because it is impossible to account for all species in the ecosystems potentially impacted, a few representative receptor groups or receptor species are typically chosen for evaluation in the screening assessment, Ecological receptors with the highest potential for exposure and/or high sensitivity to exposure should be identified. Development of a preliminary ECSM (see Section 4.2.6) in conjunction with the preliminary ecological site characterization can be used to identify these receptors. In some cases, site-specific information on receptors may be lacking, for example, due to seasonal field survey constraints. Where site-specific information on receptors present at the site is limited, generic or surrogate receptors may be used. These receptors are selected using professional judgment in a manner consistent with EPA guidance (EPA 1992a) and consideration of the following:

- Ecological relevance and the assessment endpoints.
- Regulatory significance.
- Relative species sensitivities to the contaminants.
- Mensurability and predictability.

The evaluation of potential exposure pathways is one of the primary tasks of the preliminary ecological characterization. Most ecotoxicological information is currently directed toward the quantification of exposure levels for terrestrial flora (uptake) and fauna (ingestion) and for direct contact of water by aquatic organisms. While other routes may be important (e.g., inhalation and dermal absorption by mammals), they are typically not addressed in the preliminary risk screen. The risk screen focuses on those pathways with maximum expected exposure potential based on professional judgment.

The screening assessment should specify which contaminants are of particular concern from an ecological perspective. This is generally done by comparing the screening criteria to the highest detected chemical concentrations (if enough data are available, the 95% UCL on the mean may be used).[1] The range of chemical concentrations detected, as well as the number of samples collected, should be reviewed to evaluate which approach

[1] The maximum is not necessarily the most conservative approach. For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the 95th UCL can be greater than the highest measured or modeled concentration (EPA 1992h. *Supplemental Guidance to RAGs: Calculating the Concentration Term).* In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value can be used as the concentration term. Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95% UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95% UCL is close to the sample mean).

is most appropriate. Environmental criteria only exist for a few of the many chemicals that may be found at a site. In some cases, chemicals for which criteria have been established may be used as surrogates or analogues for other chemicals at the site. EPA (19888). for example, provides guidance for using structure-activity relationships (SARs) as an analogue method for estimating toxicity to aquatic organisms. Where criteria do not exist for the contaminants and receptors in question, analysis of known toxic effects and possible threshold levels may be used to develop site-specific screening criteria against which field exposure data may be compared

To appropriately use. a screening criterion, the assessor must be aware of the assumed receptors, exposure pathways, and exposure factors used to derive the exposure concentration, as well as the nature of the screening criterion. If other exposure pathways are anticipated to be significant at a given site, use of the screening criterion is limited. If the screening criterion is based on acute toxicity and chemical concentrations in site media approach (but don't exceed) the criterion, that would be interpreted as evidence that chronic impacts could or are likely to occur.

For the screening exposure estimate, the highest estimated contaminant concentrations are used to estimate exposures to ensure that potential ecological threats will not be missed. Areas of maximum potential exposure are designated for each ecosystem (terrestrial, aquatic, wetland) or habitat. In the absence of sound site-specific information, preliminary exposure estimates are usually based on conservative assumptions such as:

- Area use is 100 percent (for a particular habitat).
- Bioavailability is 100 percent.
- The most sensitive life stage is present,
- Minimum body weight and maximum ingestion rate are used.

3.3.2 Effects Characterization

Screening level risk assessments may be largely qualitative, using simple comparisons of abiotic media concentrations to readily available screening "effects" criteria for these media, or they may employ a more quantitative investigative approach that incorporates a threshold level or dose-response assessment. In the more quantitative approach, screening level ecotoxicity values (reference diet, dose, tissue, threshold levels) are developed for the principal receptors of. concern based on the complete exposure routes. For these complete exposure routes, the lowest exposure level (e.g., concentration in abiotic media, or in diet [ingested dose]) shown to produce no adverse effects (e.g., reduced growth, impaired reproduction, increased mortality) in the receptor of concern is identified. Where no observed adverse effects levels (NOAELs) arc not available, NOAELs may be conservatively estimated from the lowest observed adverse effects level (LOAEL) or other available toxicity values. The mode of toxicity represented by the screening criterion should match the mechanism of toxicity for the contaminant in question. For example, dioxins do not exhibit acute lethality as much as they inhibit successful reproduction. Therefore the criterion for dioxins should be a reproductive measure.

Sources for obtaining ecotoxicity benchmarks in a screening assessment are generally limited to published literature and readily available criteria and information such as:

- State and Federal AWQC.
- EPA, NOAA, and Ontario sediment criteria.
- EPA on-line databases.
- ECOTOX, includes the Aquatic Information Retrieval Database (AQUIRE).
- Hazardous Substances Data Bank (HSDB) (National Library of Medicine database].
- Registry of Toxic Effects of Chemical Substances (RTECS) (National Institute for Occupational Safety and Health NOSH] database).
- Oak Ridge National Laboratory (ORNL) benchmarks.
- USAEC toxicity profiles (military compounds).
- USACHPPM information databases (military compounds).

A list of environmental resources for obtaining ecotoxicity information and values is provided in Appendix B.

3.4 Preliminary Risk and Uncertainty Characterization

Risk characterization is the screening, summarizing step of the risk assessment. The risk characterization

integrates information from the preceding components of the risk assessment, performs a screening evaluation (or calculation), and synthesizes an overall conclusion about risk that is complete, informative, and useful for decision-makers (EPA 19954). The preliminary risk (screen) characterization is used to document a decision about whether or not there is negligible potential for ecological impacts, based on the available information at this stage.

EPA has two requirements for the full characterization of risk (EPA 1995a,d). First, the characterization should address qualitative and quantitative features of the assessment. Second, it should identify the important strengths and qualitative as well as quantitative uncertainties in the assessment as part of a discussion of the confidence in the assessment. Risk characterization as the final process in the ERA process provides:

- Integration of the individual characterizations from the ecological effects and exposure characterizations.
- Evaluation of the overall quality of the assessment and the degree of confidence in estimates of risk and conclusions drawn.
- Description of risks in terms of extent, severity, and probable harm.
- Communication of risk assessment results to the risk manager.

Although several approaches can be used to assess risk, for the preliminary risk screen, comparisons of available criteria and/or screening ecotoxicity values to maximum conservative exposure estimates is considered adequate by EPA, where a quantitative approach is called for. The preliminary risk screen employs a conservative approach to ensure that potential ecological threats are not overlooked. In general, if the 95% UCL or maximum chemical concentration exceeds the screening criterion, further assessment of the site is probably indicated.

Particularly critical to full characterization of risk is a clear and open discussion of the uncertainty in the overall assessment and in each of its components. The discussion of uncertainty should highlight those uncertainties which would tend to reduce the degree of confidence in the conclusions drawn and therefore lessen confidence that the site can pose no threat whatsoever. A discussion of uncertainty requires comment on such issues as the quality and quantity of available data, gaps in the database for specific chemicals, quality of the measured data, use of default assumptions, incomplete understanding of general biological phenomena, and scientific judgments or science policy positions that were employed to bridge information gaps (EPA 1995d). In the screening ERA, the extent of the exceedance of the screening criteria, and the appropriateness of the screening value itself, help clarify uncertainty and should be evaluated as part of the initial screen decision-making process.

In the risk characterization and uncertainty discussion, the risk assessor should also try to distinguish between variability and uncertainty. Variability arises from true heterogeneity in characteristics such as dose-response differences between species and individuals, or differences in contaminant levels in the environment. Uncertainty, on the other hand, represents lack of knowledge, or data gaps, about factors such as adverse effects of select contaminants on select species. As a minimum requirement, the potential effect of the following uncertainty factors should be discussed:

- Uncertainties associated with the (limited) chemical database for the site (availability of site-specific data for medium of concern).
- Use of the 95% UCL or maximum chemical concentration for representing the site.
- Use of surrogate or generic receptors and worst-case exposure scenarios.
- Use of screening criteria and the associated assumptions.

The need for additional risk clarification beyond that of the screening ERA is based on project planning and scoping discussions by the risk assessors and risk managers. The baseline ERA process described in Chapters 4 through 7 includes the same elements as the screening ERA described above, but is more focused, detailed, and quantitative in its characterization of receptors, chemicals of concern, exposure pathways, effects, and uncertainty.

Chapter 4
Evaluating the Tier I Baseline Ecological Risk Assessment

4.1 Introduction

This chapter introduces the conceptual and technical objectives for evaluating a Tier I baseline ERA. The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical concentration-based approach. The Tier I ERA emphasizes adverse effects to the individual based on literature-cited toxicity values with extrapolations to potential impacts at the population, community, or ecosystem level. The Tier I ERA provides quantitative chemical information for the exposure point media (e.g., soils, sediments, surface water) and possibly qualitative biological data to fill gaps in the available data set. Field or laboratory bioassays are typically not part of a Tier I effort. Any biological samples collected are co-located to the extent possible with abiotic media samples. The Tier I ERA includes the establishment of appropriate ecological endpoints (ecological components affected by chemical exposure) for the chemicals of potential concern. Tier I activities are essentially a more advanced form of screening with emphasis on the following:

- Compiling and evaluating available data and information.
- Identifying critical information gaps.
- Determining the need for design and implementation of remedial activities.
- Ascertaining the need for detailed field studies prior to design and implementation of remedial activities.

Development of a site-specific ECSM, selection of potential COECs, and a description of exposure pathways are major activities in this tier. Qualitative and quantitative data from a site reconnaissance or field survey of flora and fauna are summarized in an ecological site description. This field visit coupled with site-specific information provides for documentation of obvious adverse effects, identification of potentially important receptors, and development of simplified food web models to evaluate the potential for COECs to bioaccumulate in receptors of concern.

Abiotic concentration data are used to establish exposure concentrations for the receptors of concern. Preliminary effects estimates are based on regulatory and literature values. Quotient calculations in conjunction with available toxicity information, exposure concentrations, and reasonable, conservative assumptions are used to provide initial risk estimates.

The main output from Tier I is a detailed, site-specific technical report, If the information provided by the Tier I ERA is adequate to support decisions in the FS/RD-RA, no further ERA sampling or analyses are needed. If, however, there are insufficient data (i.e., too much uncertainty in the ERA) to reach FS/RD-RA decisions, additional biotic and abiotic data needs will be identified, the data collected, and a more definitive assessment performed within Tier II, III, or IV.

In the following sections of this chapter, the individual steps required to prepare a Tier I ERA are introduced and discussed. Exhibits and a case study (CS) are also provided to illustrate the performance of these various steps (see CS 1). Exhibits are located after Chapter 9. The steps to perform a Tier I ERA are grouped as follows, in general accordance with EPA's *Framework:*

- PROBLEM FORMULATION:
  Ecological site description
  Chemical data collection and review
  Selection of preliminary COECs
  Selection of key receptors
  Ecological endpoint (assessment and measurement) identification
  ECSM
- ANALYSIS PHASE -

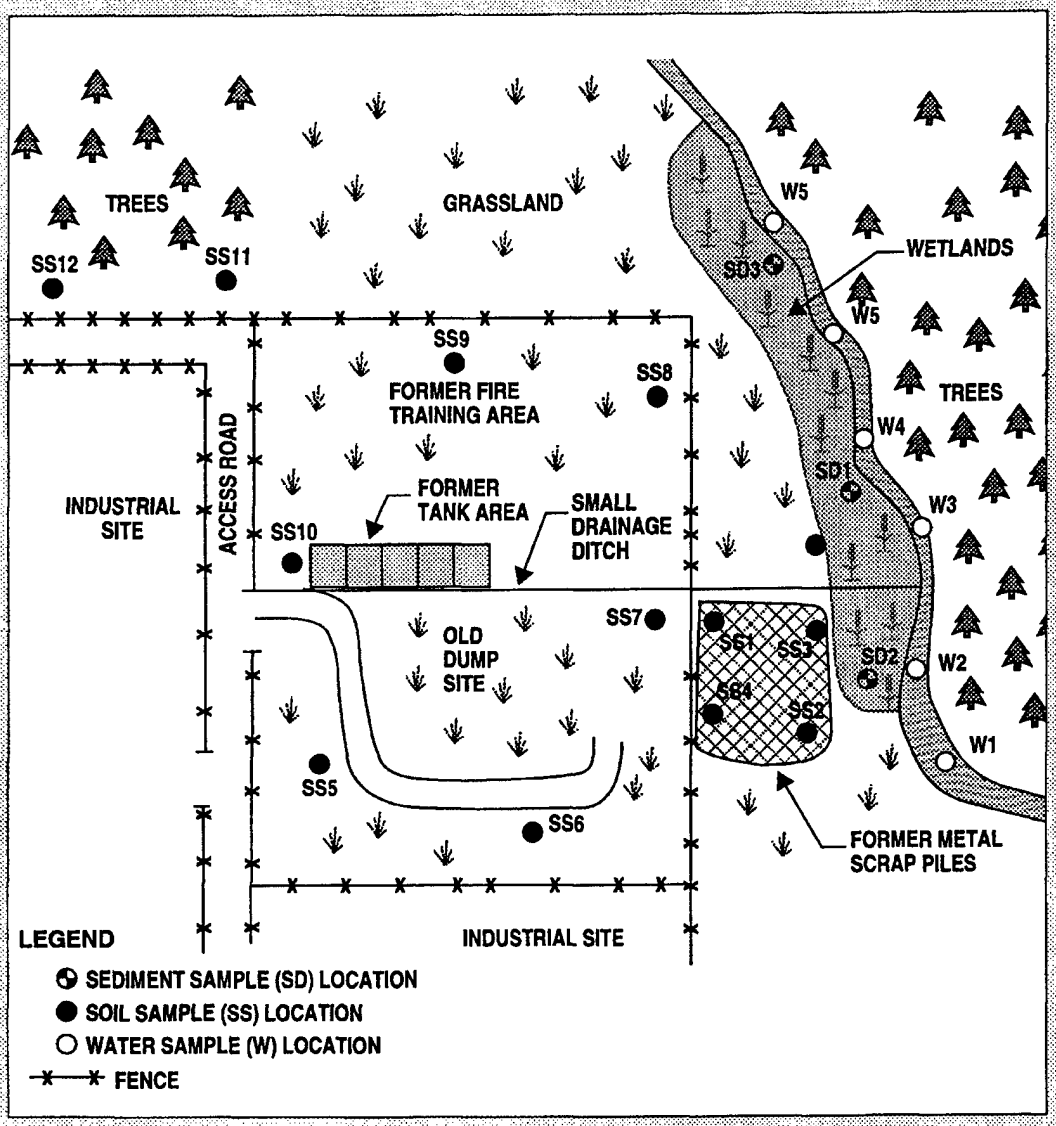
  EXPOSURE CHARACTERIZATION:
  Exposure analysis
  Exposure profiles

  ECOLOGICAL EFFECTS CHARACTERIZATION:
  Selection of literature benchmark values
  Development of reference toxicity values
- RISK CHARACTERIZATION:
  Risk estimation
  Risk summary
  Uncertainty characterization

CASE STUDY 1

SITE SETTING

For the purposes of demonstrating performance of a baseline ERA, a case study is provided throughout this section. Major steps in the ERA process are demonstrated in the following pages.



Our case study site is a former fire training area of a formerly used defense (FUD) site. The site contained a gasoline storage area near an old dump site. It is believed that only gasoline was stored in the tanks but the old records have been lost, and storage of other petroleum products or solvents may have occurred. Records on materials placed in the old dump site were also not available. There is some anecdotal information suggesting that chlorinated solvents were also dumped or burned. The gasoline storage tanks have been removed. A portion of the old dump contained some metal scrap piles that have been removed. The site is being investigated for possible chemical releases to the surrounding environment. As part of the site investigation, a baseline ERA is being performed to determine whether the chemical releases, if any, pose adverse ecological risks.

The setting of the site is shown above in this case study. The area east and north of the site is a mixture of undeveloped grassland and woodland. A small drainage ditch between the old dump site and fire training area leads to a small stream and wetland area of about 5 acres.

A preliminary investigation/site assessment (PA/SI) was performed by the state, providing the following information:

- When tanks were removed, they were found to contain holes;
- Soils in the tank excavation pits were tainted and had a petroleum odor;
- Surface soils were sampled at two locations (SS1 and SS2) during the PA/SI and analyzed for metals only. Soils were found to contain arsenic, barium, cadmium, nickel, and lead. No information on background soil quality is available.

As the risk assessor for the site, you have been asked to provide input into the development of the sampling and analysis plan (SAP), the quality assurance project plan (QAPP), and subsequent investigations.

The sequence of steps presented above is similar to the format used in most ERA documents. The actual sequence of events followed in the conduct of an ERA, however, can be quite variable and is frequently dependent on data availability, time availability, and the individual nature of the site and project. While the steps listed above are generally the same in each of Tiers I through IV, each may receive different emphasis depending on the tier and hence level of complexity of the baseline ERA.

4.2 Problem Formulation

Problem formulation is used to establish the goal, scope, and focus of the Tier I ERA. This systematic planning phase identifies the major factors to be considered in evaluating ecological risks associated with a given site and its linkage to the regulatory and policy context of the assessment. Problem formulation provides an early identification of key factors to be considered in the Tier I ERA. The problem formulation stage thereby encompasses the creation of PD statements to represent the specific planning objectives of the Tier I effort.

Once triggered, the problem formulation process begins a preliminary (largely conceptual) characterization of exposure and effects. This involves evaluating the potential COECs present, the ecosystems and receptors potentially at risk, the ecotoxicology of the contaminants known or suspected to be present, and observed or anticipated ecological effects. Then, ecological endpoints to be addressed and/or measured are identified (see Section 4.2.5). The process culminates in a preliminary ECSM that identifies potential exposure pathways, environmental values (receptors) to be protected, impacts or adverse effects to be evaluated, data needed, and analyses to be used (see Section 4.2.6).

4.2.1 Ecological Site Description

An initial site description is needed to orient the technical specialists. This information should be assembled from existing sources of information, without conducting formal field studies. Initially, base or facility natural resource personnel should be contacted as they often have relevant data or useful ecological information. Many state and Federal agencies can provide information on sensitive areas or regional data on ecology, especially threatened and endangered species, checklists of biota, endemic species, and other pertinent ecological information. These agencies include USFWS, local and state planning agencies, 404 staffs in EPA regions, state fish and wildlife agencies, and perhaps the new USDOI National Biological Survey in the near future. Surveys conducted by the Nature Conservancy or state Natural Heritage Programs may also be available.

Much information may be available from published sources such as soil survey and topographic maps, National Wetlands Inventory Maps (NWI), and information from natural history or heritage program databases or from previous assessments of the site. In addition, experts at local or regional universities often can provide information on wetland species, bird checklists, mollusks, plants, or other specialties. Local, regional, or university museums or state biological surveys may be other sources of information.

Presence of wetlands, threatened or endangered species, endemic species, or lands or waters containing species considered as or classified as having a "high" value will significantly impact problem formulation and planning for conduct of the ERA. Where waters of the state are involved, the National Pollutant Discharge Elimination System (NPDES) permitting agency may be a good source of information especially if they have conducted use attainability studies for the purpose of classifying the uses or have permitted discharges to the waters.

4.2.1.1 Reconnaissance (Biota Checklist)

Much of the information sought during a site reconnaissance is commonly available information. However, it is essential that a site reconnaissance and ecological site characterization be conducted in this stage by an ecologist.

Prior to arrival at the site, the ecologist should be provided with information on the site, including topographic maps; township, county or other appropriate maps: location of potential ecological units such as streams, lakes, forest, grasslands, floodplain and wetlands on or near the site: soil types: and local land uses. Much of this information may already have been obtained and documented as part of the PA/SI effort. A checklist with information similar to that on EPA's (1993a) ***Checklist for Ecological Assessment/Sampling*** should be completed, if it was not completed as part of the PA/SI.

The location of known or potential contaminant sources affecting the site and the probable gradient or pathway by which contaminants may be released from the site to the surrounding environment should be determined to the extent possible based on observations and available information from earlier studies (i.e., PA/SI or RFA). If waters of the state or the U.S. are potentially involved, their designated uses should be determined, so that the

ecologist can make a preliminary qualitative determination as to whether such uses are apparently being achieved.

Ecologists can use the reconnaissance to evaluate the site for more subtle clues of potential effects from contaminant release. For example, the noticeable absence of flora or fauna where otherwise expected may be a clue to potential contaminant effects or other stressors. Absence of the flora understory from a forest may be an indication of soil contamination and the inability of shorter lived forbs and shrubs to reestablish themselves. On the other hand, unusually high numbers of a particular species or unusually thick accumulation of litter may indicate the absence of predators or disruption of nutrient cycling processes. Such ecological observations are important clues to DQO development, the data interpretation effort, and the weight-of-evidence presented in the subsequent risk characterization.

4.2.1.2 Documentation of Potential Receptors of Special Concern and Critical Habitat

The site reconnaissance, in combination with published resources, and information obtained from state and Federal fisheries and wildlife agency experts, should be used to determine if the site or nearby site areas have designated wetlands or critical or sensitive habitats for threatened or endangered species. If such species or entities are present, they must receive special protection during all aspects of the project planning and implementation following consultation with appropriate regulatory authorities.

During the reconnaissance, a checklist of biological species should be developed. From this list, receptors of special concern will be identified. Depending on the sources and potential transport pathways, these receptors could include major elements of the given food chain from plants to higher trophic levels such as insects, reptiles, birds, and mammals. Aquatic ecosystems, for example, can include aquatic plants, bottom fauna (e.g., insects, mollusks), amphibians, turtles, piscivorous snakes, fish, wading birds or ducks, and predatory raptors.

Receptors am the components of ecosystems that are or may be adversely affected by a chemical or stressor. In the Tier I investigation, species, species groups, functional groups (e.g., producer, consumer, decomposer), food guilds (i.e., organisms with similar feeding habits), and critical habitats are the focus of receptor selection. Receptors can be any part of an ecological system, including species, populations, communities, and the ecosystem itself. Toxicity of chemicals to individual receptors can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by chemicals, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Because it is difficult to assess potential impacts to all receptors, a smaller group of receptors of concern (key receptors) is used to assess potential harm to all components of the system. In the Tier I ERA, specific organisms or groups (e.g., small herbivores) are usually selected as key receptors.

4.2.1.3 Significant Ecological Threats

The questions the risk assessor must keep in mind are "Do any ecological threats exist?" and "Are these ecological threats related to chemical contamination?" Using the information discussed above, the risk assessor can begin to identify the habitats potentially affected by contaminants at the site. Decisions can be partly based on absence of biota where expected, especially if plant or animal life is absent along likely contaminant exposure pathways. For example, if areas within the project exposure pathways(s) are devoid of plant life or are obviously stressed, a significant ecological threat probably exists. If there is a groundwater or surface water discharge zone to a stream that is affected by site chemicals and depleted of biota, that would be an obvious significant ecological threat. If effects are less obvious, then it may be necessary to use a more sophisticated approach to determine any impacts, such as a comparison of site biota diversity and relative numbers to an unaffected reference site within or adjacent to the watershed.

4.2.2 Chemical Data Collection and Review

Planning, collection, and review of chemical data constitute the initial and often the most substantial level of effort in a Tier I ERA. Because of the importance for obtaining useable data to the end goal of an acceptable ERA, the following sections describe the data collection and review process in detail (including elements as described in the HTRW technical project planning guidance document).

4.2.2.1 Planning and Providing Input to Data Collection

The ecological risk assessor can effectively contribute to the data collection process when he/she is involved early

on and has some information regarding the ecological setting and the contamination history of the site. To effectively contribute to the overall data collection and analysis process, the risk assessor should be knowledgeable and experienced with the overall DQO process.

To plan and provide input to the data collection effort, the risk assessor should follow the three DQO steps recommended by EPA (1989c) ***in*** the ***Field and Laboratory Reference Document.*** Step I of the process includes preparing definitions of the problem and concise (as possible) statements of the questions to be answered. Examples of Step I DQOs include the following:

- Identify potential and appropriate site-specific receptors, potential COECs, and potential exposure pathways to assess the potential for adverse effects to occur to biological resources as a result of contamination.

- Evaluate the potential for impacts to occur to biological resources outside the current site boundaries.

- Evaluate the need for remediation to protect the environment.

Steps II and III of the DQO process include identification of data needed to answer questions identified in Step I and design of the data collection program (i.e., the data quality design process). Products of Step II include proposed statements of the type and quality of environmental data required to support the DQOs, along with other technical constraints on the data collection program. The objective of Step III is to develop data collection plans that will meet the criteria and constraints established in Steps I and II. Step III results in the specification of methods by which data of acceptable quality and quantity will be obtained (ER 1110-1-263). The DQO development process is flexible and may continue throughout the baseline ERA.

Data needs for the ERA are likely to overlap with those for the human health risk assessment or other data users in specific physical areas of a site. The potential for data need overlaps should be identified early on. Nearby surface waterbodies that are potentially linked to the source through chemical fate and transport are typically sampled for human health purposes. Sediment samples may also be desired by the human health risk assessor, but human exposure points may be different from ecological ones, so proposed sample locations should be reviewed. The ecological risk assessor may need water and sediment samples from specific locations such as where waterfowl are feeding or where effects on benthic communities are likely to occur. Similar data needs should be determined early on by the human health and ecological risk assessors for the elimination of unnecessary work or redundancies in sampling.

Development of a preliminary ECSM is useful in planning for identifying data that will be needed (i.e., sampling and analysis plan) in the ERA (see Section 4.2.6) (see CS 2 and CS 3). An ECSM identifies the likely source(s) of chemicals, the chemical release mechanisms, fate and transport potential, and the resultant secondary and tertiary media that may be impacted. The ECSM also (1) identifies plausible food webs at the site, (2) identifies all potential pathways from chemicals at the source to receptors of concern, and (3) evaluates the completeness of potential exposure pathways, based on known nature and extent of contamination and ecology of species and communities potentially occurring at the site. In essence, the ECSM describes the exposure pathways or routes a chemical takes from point of release from the chemical source to receptors of potential concern. The ECSM is thus a summary of some portions of the exposure characterization. By identifying the potential abiotic media that may need to be assessed in the ERA, and the potential exposure routes by which ecological receptors may be exposed, the ECSM can identify the type of data needed in the ERA. Section 4.2.6 discusses the ECSM in more detail.

Historical data collected for purposes other than the ERA may be available from previous investigations, facility records, permit applications, or other sources. Often, use of historical data sets is limited by the lack of information on sample locations, analytical methods, detection limits, laboratory and quality assurance/quality control (QA/QC) procedures, or scope of analyses. Data from historical sources, therefore, may not be appropriate to use in the quantitative ERA; however, they often can be used in a supportive, qualitative role. When evaluating historical or purposely collected data, a number of factors need to be evaluated. Some factors that should be considered are presented in Exhibit 2.

On the other hand, unique data needs may also be identified early on in the PA/SI or Tier I ERAs that would require purposive (biased) sampling in order to collect abiotic samples from specific areas of contaminant or ecological concern. Onsite animal activity should be initially observed to best evaluate obvious activity patterns relative to the contaminant source areas. For example, if

CASE STUDY 2

DEVELOPMENT OF A PRELIMINARY ECOLOGICAL CONCEPTUAL SITE MODEL

The first step in developing a credible sampling design to support the risk assessment is to formulate an ecological conceptual site model (ECSM). Development of an ECSM is discussed in Section 4.2.6, which should be consulted in conjunction with this case study step. First, some hypothesis of chemicals potentially present on site is needed.

The existence of gasoline or petroleum tanks and possible disposal of solvents suggest the following chemicals may be present:

- Benzene, toluene, ethylbenzene, xylenes (BTEX)
- Polycyclic aromatic hydrocarbons (PAHs)
- Trichloroethylene and other chlorinated solvents

The surface soil analyses detected the following metals:

- Arsenic
- Barium
- Cadmium
- Nickel
- Lead

In order to evaluate how and where chemicals may migrate from the site, and in what media the chemicals may be located, the following information is needed for each chemical:

- Water solubility (S);
- Tendency to bind to soil (K_{oc});
- Tendency to accumulate into animal tissue (BCF); and
- Volatility (vapor pressure or Henry's Law Constant).

Obtain these chemical and physical parameters, and anticipate how the potential chemicals may be released and migrate from the site. Then, develop a preliminary ECSM, starting with the primary source areas and progressing to secondary and tertiary sources, and through specific release and migration mechanisms.

CASE STUDY 3

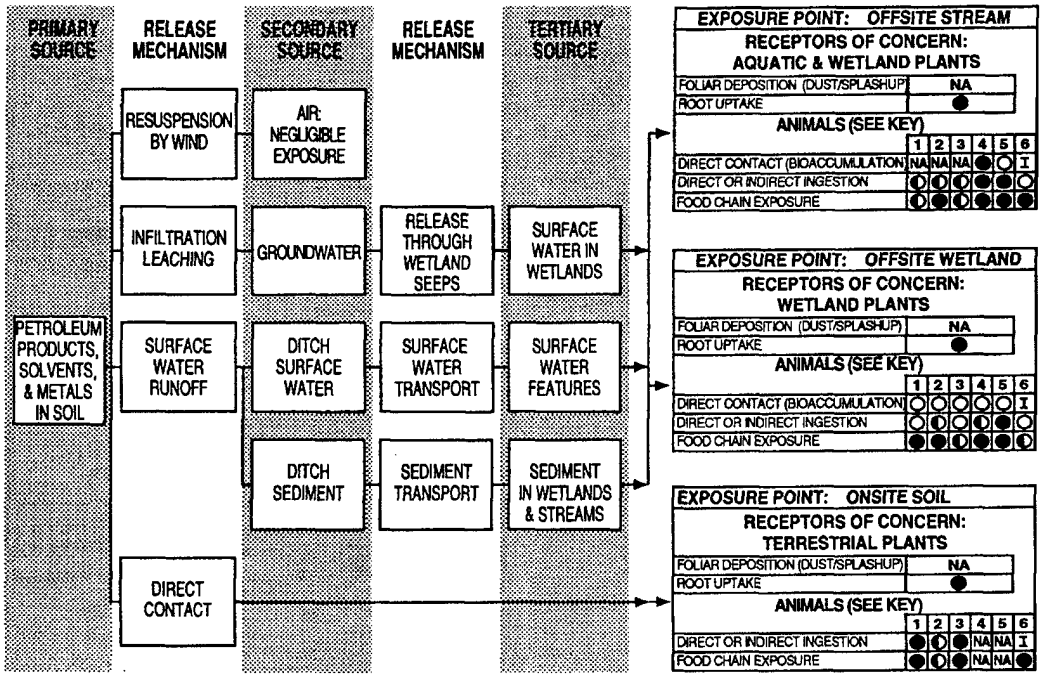
DIAGRAMMING THE ECSM

The ECSM is developed and diagrammed by examining the sources of chemicals and possible release mechanisms, based on an understanding of the fate and transport characteristics of chemicals potentially present on site. A diagram of the ECSM is shown in Example 1 ECSM.

Primary Sources

Preliminary information suggests four possible sources of chemical release to the environment: (1) the former tanks, (2) the old site, (3) the old burn pit, and (4) scrap metal piles. Release at each of these sources may have contaminated soils at the site. Because the original sources have been removed and operations have ceased, soil is considered the primary source of potential contaminant release to the environment.

Example 1 ECSM



KEY TO WILDLIFE RECEPTORS OF CONCERN

① MAMMALIAN HERBIVORES
② MAMMALIAN OMNIVORES AND CARNIVORES
③ AVIAN OMNIVORES
④ AQUATIC INVERTEBRATES AND INFAUNA (ANIMALS)
⑤ WADING BIRDS
⑥ PREDATORY RAPTORS

KEY TO EXPOSURE PATHWAY SIGNIFICANCE

NA NOT APPLICABLE
I INCOMPLETE
○ EXPOSURE POTENTIAL RELATIVELY LOW
◐ EXPOSURE POTENTIAL INTERMEDIATE
● EXPOSURE POTENTIAL RELATIVELY HIGH

Primary Release Mechanisms

Preliminary information suggests the following release mechanisms:

- Resuspension by wind;
- Infiltration and leaching to groundwater from the burn pit, tank area, and scrap piles;
- Surface water runoff from the tank area and scrap piles; and
- Direct contact with site soils.

Secondary Sources

Primary releases from contaminated soils may have resulted in secondary contamination of the following environmental media:

- Groundwater beneath the site;
- Surface water in the ditch;
- Sediments in the ditch or adjacent stream and wetlands; and
- Air.

Due to ecological and climatic conditions, exposure to airborne contaminants is usually considered negligible with respect to the other primary exposure pathways. Lichens, however, are one example of a receptor group that is exceptionally sensitive to airborne contamination.

Secondary Release Mechanisms

Fate and transport information suggests the following secondary release mechanisms:

- BTEX and solvents in groundwater may be released to surface water at the wetland seeps;
- Metals and organic contaminants in ditch surface water may be transported in surface water to the wetland and stream;
- Metals, PAHs, and other organic contaminants in sediment may be transported to the wetland and stream; and,
- BTEX and solvents in soil or groundwater may volatilize to air (not shown in ECSM).

Tertiary Sources

From the above secondary release mechanisms, the potential tertiary sources are:

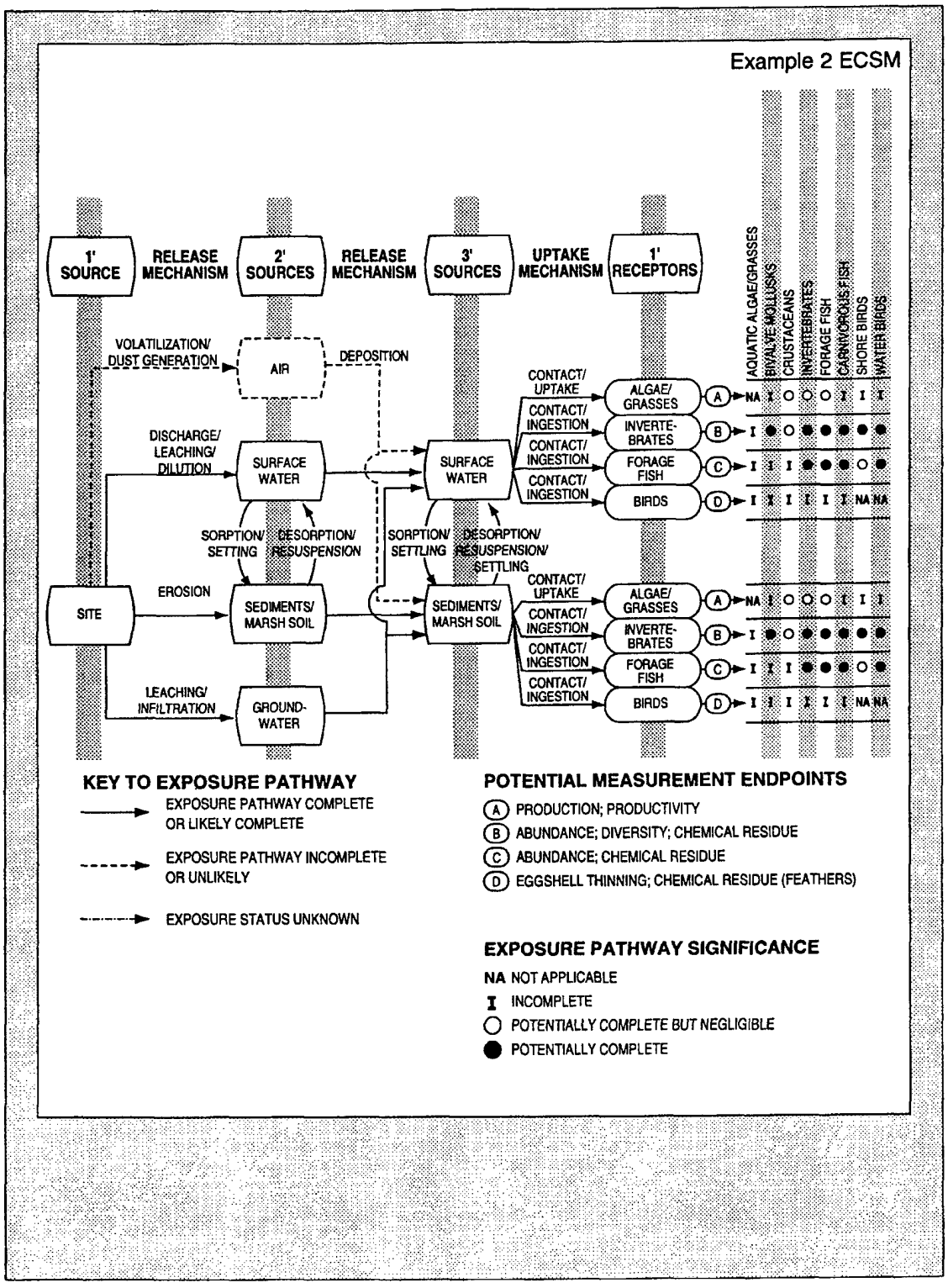
- Surface water in wetlands and the stream; and
- Sediments in wetlands and the stream.

Primary Potential Exposure Pathways

The primary potential exposure pathways for ecological receptors include the following:

- Ingestion of surface soils (on-site);
- Root uptake from soil by terrestrial plants;
- Root uptake from water or sediment by aquatic and wetland plants;
- Direct contact/bioaccumulation from surface water by aquatic animals;
- Ingestion of surface water;
- Ingestion of sediments; and
- Food chain exposure.

This completes the preliminary ECSM. An additional ECSM diagram is shown in Example 2 ECSM.


Example 2 ECSM
1' SOURCE
RELEASE MECHANISM
2' SOURCES
RELEASE MECHANISM
3' SOURCES
UPTAKE MECHANISM
1' RECEPTORS
AQUATIC ALGAE/GRASSES
BIVALVE MOLLUSKS
CRUSTACEANS
INVERTEBRATES
FORAGE FISH
CARNIVOROUS FISH
SHORE BIRDS
WATER BIRDS
VOLATILIZATION/ DUST GENERATION
AIR
DEPOSITION
DISCHARGE/ LEACHING/ DILUTION
SURFACE WATER
SURFACE WATER
SORPTION/ SETTING
DESORPTION/ RESUSPENSION
SORPTION/ SETTLING
DESORPTION/ RESUSPENSION/ SETTLING
SITE
EROSION
SEDIMENTS/ MARSH SOIL
SEDIMENTS/ MARSH SOIL
LEACHING/ INFILTRATION
GROUND-WATER
CONTACT/ UPTAKE
CONTACT/ INGESTION
ALGAE/ GRASSES
INVERTE-BRATES
FORAGE FISH
BIRDS
A
B
C
D
KEY TO EXPOSURE PATHWAY
EXPOSURE PATHWAY COMPLETE OR LIKELY COMPLETE
EXPOSURE PATHWAY INCOMPLETE OR UNLIKELY
EXPOSURE STATUS UNKNOWN
POTENTIAL MEASUREMENT ENDPOINTS
(A) PRODUCTION; PRODUCTIVITY
(B) ABUNDANCE; DIVERSITY; CHEMICAL RESIDUE
(C) ABUNDANCE; CHEMICAL RESIDUE
(D) EGGSHELL THINNING; CHEMICAL RESIDUE (FEATHERS)
EXPOSURE PATHWAY SIGNIFICANCE
NA NOT APPLICABLE
I INCOMPLETE
○ POTENTIALLY COMPLETE BUT NEGLIGIBLE
● POTENTIALLY COMPLETE

receptors of special concern are observed on site, it may be advisable to collect chemical sample(s) from their specific habitat.

The need to detect contaminants at extremely low concentrations may also be a unique data need for the ERA. For example, some polycyclic aromatic hydrocarbons (PAHs) (naphthalene, benzo-a-pyrene, and phenanthrene) have reported effects levels in sediments below the certified reporting limits (CRLs) for these chemicals. Also, matrix effects interference in soil and sediment sampling often results in detection limits well above ecological effects levels. While it may be desirable, it is not always possible to have the CRLs or detection limits lower than the effects levels. Such considerations, however, are important to the data collection planning process, the data interpretation, and resultant risk characterization.

The risk assessor's data needs definition for a site is the culmination of the assessor's effort to conceptualize and develop a strategy for conducting the baseline ERAs, based on available chemical and ecological information. Often, the ecological risk assessor is invited to merely comment or advise on a sampling program that has already been devised for other users. Other times, the ecological risk assessor may be largely responsible for design of the entire sampling program. The level of effort for this task may range from minimal to large and complex. Further details on technical project planning and designing a data collection program for an ERA are presented in the following section and in EM 200-1-2 HTRW *Technical Project Planning* document USACE (1995b).

4.2.2.2 Evaluation of Available PA/SI Chemical Data

Quality chemical data from the PA/SI data collection effort should be available for use during problem formulation and conduct of the Tier I ERA. Knowledge about historical use of the site should provide information about potentially present contaminants. Available PA/SI chemical data and physicochemical data (organic carbon content, pH, etc.) for abiotic media are used in the screening process to compare measured values with selected toxicity benchmarks for those media. This information in concert with observations made during the reconnaissance and professional judgment are used to characterize risk and evaluate the potential need for a Tier II, III, or IV ERA.

The need to proceed to Tier II biological sampling could be indicated by exceedance of the toxicity benchmarks or other regulatory criteria or by the presence of organic chemicals that biomagnify. Organic chemicals with bioconcentration factors (BCFs) greater than 100 (on a 3% mean lipid content) or log K_{ow} (logarithm of the n-octanol water partition coefficient, log P) values greater than 3.5 are of greatest concern (EPA 1991e) due to their potential to biomagnify in ecological systems. Organic chemicals with BCFs greater than 300 are considered to be of significant concern in aquatic ecosystems, while for terrestrial organisms, BCFs as little as 0.03 can be significant if the residue is toxic (EPA 1989a). Chemicals with water solubilities less than 50 mg/L and potential for significant partitioning into environmental media other than air and water would also be of concern. The presence of chemicals that can biomagnify generally results in a greater level of effort for characterizing risk in Tier I or in the need to proceed to Tier II biological sampling.

Care should be taken where data collected during the PA/SI are largely intended for use in the human health risk assessment, as detection limit needs can be different for the two assessments. For example the drinking water criterion for copper is 1.3 mg/L, while the chronic aquatic life criterion for copper at 100 mg/L $CaC0_3$ hardness is much lower (12 pg/L). Conversely, some of the listed carcinogenic organic compounds are relatively nontoxic to aquatic life, but have extremely low human consumption criteria limits. The PA/SI environmental media data should be evaluated to determine whether chemical concentrations exceed ARARs or guidance criteria. Where data gaps are identified (e.g., chemical data are not available for the location or media of ecological interest), then planning for additional data collection should be undertaken (see CS 4).

4.2.2.3 Review of Analytical Data

The quality of an ERA depends directly on the quality of the chemical data applied. Regardless of how well other components of the Tier I ERA are performed, if data quality is poor or data do not accurately reflect site contamination or the types of exposures assessed, the Tier I ERA will not provide an adequate description of potential adverse ecological effects posed by the site. Therefore, it is imperative that data types used in the assessment be carefully evaluated and properly used.

Planning for appropriate data acquisition is an important step in obtaining the necessary, high quality data. During this planning stage, appropriate location, number and types of samples, detection limits, and analytical methods can be specified as part of the DQQ process. These and

CASE STUDY 4

DEVELOPMENT OF A SAMPLING AND ANALYSIS PLAN

Evaluation of the existing data for our site has concluded the following:

- Releases of metals to surface soils, surface water, and sediments have potentially occurred;
- Petroleum/solvent releases to surface and subsurface soils have occurred; and
- Volatile organic compound releases to groundwater and subsequent release to wetland and creek sediments and surface water may have occurred.

The ECSM suggests the following:

- Volatile and semivolatile organic compounds may be present in the soil; and
- Semivolatile organic compounds and metals may be present in the soils, sediments, and surface water over a greater area than expected.

The following data gaps are identified:

- There are no data on volatile or semivolatile organic compounds in surface or subsurface soils and metals data in soils are limited;
- There are no surface water or sediment data for organic compounds or metals; and
- Information on groundwater flow direction is not available.

Data quality objectives for additional sampling include:

- Collection of additional soil samples for metals, volatile and semivolatile organic compounds;
- Collection of sediment and surface water samples for metals, volatile and semivolatile organic compounds;
- Collection of groundwater samples for metals, volatile and semivolatile organic compounds and for water table levels; and
- Collection of background surface soil, groundwater, surface water and sediment samples.

other minimum requirements for ERA data should be specified prior to data collection by having the risk assessor involved in early stages of site planning. Once available, a thorough review of the data is needed to ensure that DQOs and minimum requirements have been met. This further ensures that the most appropriate information is used in the ERA.

Numerous factors may potentially have to be considered when identifying minimum data collection requirements for an ERA, or when reviewing existing data to determine useability in an ERA. Relevant guidance on data useability in ERAS is published in the following EPA documents (also see Appendix B):

- *Guidance for Data Useability in Risk Assessments* (Parts A and B) (EPA 1992d,e)
- *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis* (EPA 1994c)
- *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis* (EPA 1994d)

An evaluation of data quality should examine the following five broad categories:

- Data Collection Objectives (discussed above).
- Documentation.
- Analytical Methods/Quantitation Limits (see Exhibit 3).
- Data Quality Indicators (see Exhibit 4).
- Data Review/Validation (see Exhibit 5).

Each of these categories contain other factors that should be considered, as well. In some cases, portions of the evaluation are performed by practitioners other than the risk assessor (for example, data validation is most often performed by a qualified chemist): in other cases, the risk assessor must take the lead in acquiring and reviewing the information. In either case, the risk assessor must be aware of the important factors within each category to enable him or her to judge whether the data are appropriate for inclusion in an ERA. Further discussion of the data quality evaluation process is presented in Appendix D (HTRW *Technical Project Planning Process).*

4.2.2.4 Data Presentation and Summary

Data that have been identified as acceptable for use in the Tier I ERA should be summarized in a manner that presents the pertinent information to be applied in the ERA (see CS 5). Any deviations from the DQOs or minimum requirements should be identified, and the potential effect upon the ERA described in the assessment. Any data that have been rejected as a result of the data evaluation should be identified, along with a reason for their rejection.

At this point in the Tier I ERA, all appropriate site data identified as acceptable by the data evaluation process should be combined for each medium for the purposes of selecting preliminary COECs for the site, as discussed in the next section. However, this does not mean that all available data are to be combined. "Appropriateness" of data should take into consideration the area of exposure to be assessed.

An exposure area can be defined as the area in which a receptor will be exposed to a medium through one or more exposure pathways. The boundaries of the exposure area depend on the available pathways for exposure and the habitats potentially exposed to contamination. An exposure area may be the entire site if chemical contamination is widely dispersed, or it may be a small subsection of the site if chemical contamination is localized. The exposure area may be a downwind/downgradient area for air, soil, or surface water exposure. Because the exposure area is a function of receptor foraging range as well as a real extent of contamination, the exposure area may include portions of the site that have not been impacted by specific chemicals that are being assessed. For example, if a former tank area is being assessed within a larger site, soil samples from the general tank area should be considered as a discrete exposure area and should not be combined with other site soils that are remote from the tank area. When unrelated areas of the site are combined with impacted areas, detection frequency and exposure point concentrations can be biased low. It would be appropriate, however, to include samples from within the defined tank area that are reported as nondetected with the contaminated samples from within the same area since these samples are within a defined exposure area. Under some circumstances, however, inclusion of unrelated areas may be acceptable where doing so provides a more realistic foraging-exposure area for a receptor population of concern.

CASE STUDY 5

SAMPLING RESULTS (TERRESTRIAL ECOSYSTEM)

The following soils data were obtained from site sampling.

Soil Sample Location	Acetone (ug/kg)	Arsenic (mg/kg)	Cadmium (mg/kg)	Nickel (mg/kg)	Lead (mg/kg)	Barium (mg/kg)
SS1	5 B	7.8	100	20	4	302
SS2	2 BJ	6.2	92	16	17	314
SS3	5 U	5 U (2.5)	78	19	16	356
SS4	5 B	10.3	75	15	19	396
SS5	5 U	4.9 J	42	12	13	377
SS6	2 BJ	11.4	51	19	15	342
SS7	6 B	5 U (2.5)	33	21	18	309
SS8	3 BJ	7.9	29	17	18	433
SS9	5 U	9.4	53	18	14	395
SS10	3 BJ	5 U (2.5)	48	14	16	302
SS11 (background)	7 B	8.4	32	19	19	392
SS12 (background)	4 BJ	6.2	56	16	13	376

B = Analyte found in associated blank as well as in sample
U = Compound analyzed, but not detected
J = Value is estimated
( ) = Value is 1/2 the sample 9 detection limit

Reference area locations should not be included with site samples when defining an exposure area. Reference locations are selected to represent offsite conditions and to help distinguish chemicals and ecological conditions that are site-related and those that are not. Reference samples may or may not be "clean," depending on local background conditions, global atmospheric deposition, other anthropogenic sources, or upgradient sites (i.e., other non-site-related sources of chemicals may be present), but they should not be impacted by site conditions. Reference samples should be collected from locations unimpacted by anthropogenic inputs, to the greatest degree reasonably possible. Reference areas may be used to establish background chemical concentrations, if appropriate criteria are used to select the reference areas. Further discussion on use of background determinations is presented in Section 4.2.3.3.

4.2.3 Selection of Preliminary Chemicals of Ecological Concern

COECs are those chemicals that can potentially induce an adverse response in ecological receptors. Because not all chemicals found at a site will have adverse effects on biota, the list of chemicals to be evaluated can be narrowed Chemical, physical, ecological, and toxicological criteria are used in evaluating preliminary COECs. COECs typically include: (1) chemicals that are not laboratory contaminants (i.e., chemicals whose detection has not been flagged as a result of laboratory contamination), (2) chemicals that occur at higher concentrations than those found at background or reference sites, (3) chemicats that have the potential (qualitatively based on concentrations detected and toxicity) to cause acute or chronic toxicity following exposure, (4) chemicals which have the potential to bioaccumulate or biomagnify. Although the selection process for COECs parallels that for the human health risk assessment, the lists may differ somewhat based on chemical fate and transport characteristics and species-specific toxicities.

4.2.3.1 Objectives

The objective of selecting preliminary COECs for the Tier I ERA is to identify a subset of chemicals detected at the site that have data of good quality, are not naturally occurring or a result of nonsite sources, and are present at sufficient frequency, concentration, and location to pose a potential risk to ecological receptors. The selection of COECs is a process that considers site-specific chemical data in conjunction with the preliminary ECSM (see Section 4.2.6) that describes potential exposure pathways from chemical sources to ecological receptors. This selection process is needed for several reasons:

- Not all chemicals detected at a site are necessarily related to site activities. Some may be naturally occurring, a result of anthropogenic activities, or a result of chemical use in offsite areas.
- Some chemicals may be a result of inadvertent introduction during sampling or laboratory analysis.
- Disparities as well as similarities exist in the selection process for COECs and chemicals of concern to human health.
- Not all chemicals detected at a site are present at concentrations high enough to pose a potential exposure or ecological threat. Additionally there may be trace elements present at nutritionally required or ecologically protective concentrations.

The chemical selection process is performed by evaluating the data that have been identified as useable by the data evaluation process (described previously). Chemical selection involves evaluation of these data using criteria to identify those chemicals that are not appropriate to retain as COECs (see Section 4.2.3.3). Through an exclusion process, the COECs are selected from the list of chemicals analyzed in site media. The outcome of the selection process is a list or lists of chemicals in site media that will be assessed quantitatively in the ERA.

4.2.3.2 General Considerations

Two general factors should be considered before applying the chemical selection process. These factors allow the assessor to select the most appropriate data to include in the assessment.

What is the exposure area?

- Not all chemical data collected from site media represent those to which ecological receptors are necessarily exposed. When selecting COECs, the potential receptors, exposure pathways, and exposure routes identified in the preliminary ECSM should be examined. The preliminary ECSM will identify how and where exposure is expected to occur (i.e., through soil, sediment, or

water ingestion, by direct contact or indirect ingestion, etc.). This information is then used to help identify the media and locations where assessments will be directed and COECs need to be identified.

- A distributional analysis of the chemicals present at a site should be conducted. This examination would differentiate between impacted areas and nonimpacted areas. The distributional analysis may be a statistical or a qualitative evaluation. The distributional analysis may identify the whole site as the exposure area or only subunits of the site as the exposure area.

Are the chemical data appropriate?

- Even with high quality, useable data, the form of the chemical or sampling technique should be examined for useability and relevance for exposure. Federal AWQC for metals are based on total recoverable metals; measurement of dissolved metals levels would therefore not be directly comparable (although dissolved metals measurements do have a place in ERAs).[1] Filtered water samples are generally not relevant for most wildlife exposures. To apply Federal AWQC, site-specific factors associated with metals availability (e.g., total organic carbon, pH) and toxicity to aquatic life need to be collected (EPA 1993c).

Are the chemical data ecologically relevant?

- Soil and sediment samples from below a predetermined biologically relevant depth are not typically included in the terrestrial assessment. The biologically relevant depth is based on the ecology of the site and the depth to which small mammals or other receptors of concern (birds or invertebrates) on the site burrow and may therefore be exposed. Feeding habits of animals also determine the type of exposure. Data composited from multiple locations over a large area am not relevant to exposures for animals with a small home range or specific habitat preferences.

[1] EPA has published metals ratios so that comparisons can be made between dissolved and total metals concentrations *(see Water Quality Standards: States Compliance - Revision of Metals Criteria,* Interim Final Rule, 60 FR 22229 [EPA 1995f]).

4.2.3.3 Selection Criteria/Methodology

Criteria that can be applied to determine whether a chemical should be removed as a potential COEC must be fitting to the selected or anticipated ecological endpoints and the overall adequacy of the sampling program. The process for selecting COECs is not entirely standardized or mechanistic, but employs a considerable amount of professional judgment throughout the process. For example, the assessor should consider whether limited chemical distribution or limited presence is an artifact of sampling inappropriate media or locations? Were groundwater wells screened at appropriate locations to detect nonaqueous phase liquids (NAPLs; e.g., coal tars)? Could site-related COECs potentially exert similar toxic action as background "contaminants" or exacerbate the toxicity of the background "contaminants"?[2] The decision to carry forward all detected compounds into the exposure and effects characterization portions of the screening or baseline ERA is sometimes made depending on the number of chemicals detected and project scope.. More often, risk assessors chose to sequentially eliminate chemicals through the progressive application of screening criteria. Through this elimination process, the risk assessor assumes that all chemicals are addressed (not overlooked), but that only the relevant chemicals are carried forward into the quantitative risk analysis. Examples of screening criteria include the following:

- Nondetection (use of appropriate detection limits).
- Limited chemical distribution and limited presence in environmental media.
- Comparability with screening criteria (AWQC, effects range-low (ER-Ls), LELs, etc.).
- Comparability with background concentrations (consideration of site-relatedness).
- Non-site-relatedness.
- Role as an ecologically essential nutrient at site concentrations.
- Low toxicity/bioconcentration screen.

[2] Contaminants, in this case, refers to naturally occurring metals or organics or chemicals present as a result of large, regional-scale contamination.

- Low potential for bioaccumulation and biomagnification.

These criteria, which generally follow *RAGS I and II* (EPA 1989a,f). are typically applied sequentially to the available data Once a chemical is eliminated based on a screening criterion, it is not considered in subsequent screening. Each of the above criterion is discussed further in the following sections. Further explanation of the COEC selection process is provided in CS 6 and CS 7.

The ECSM will often identify two or more ecological receptors of concern, particularly where both terrestrial and aquatic ecosystems are present. In these cases, the COEC selection process is branched: one branch focuses on aquatic receptors, the other branch focuses on terrestrial receptors. Within the terrestrial COEC selection process, further branching may occur in those cases where the chemicals are known to bioaccumulate. Where there are migratory birds and higher trophic level predatory raptors present, for example, one branch would focus on the COECs that may have acute or chronic effects on migratory birds, and the other branch would focus on chemicals that bioaccumulate and may affect the top trophic level receptors (e.g., raptors).

4.2.3.3.1 Nondetection. Chemicals analyzed for but not detected in any sample of a site medium should not be included as COECs for that medium. To be selected, a chemical must be found in at least one sample of the environmental medium at a reported concentration (i.e., the results are not reported as nondetect and qualified with a "U"). To be included, a chemical must have concentrations above the sample quantitation limit (SQL), which is the lowest level that a chemical may be accurately and reproducibly quantified (EPA 1989c), or have concentrations that are quantified but estimated (i.e., less than the SQL and labeled with a "J" qualifier). Where samples have an associated duplicate analysis, the higher of the sample or the duplicate results (if both were detected) is usually presented, if both the sample and the duplicate results were not detected (ND), then the lower of the two SQLs is presented; if one result is detected and the other is ND, then the detected concentration is reported.

Care must be taken when evaluating analytical results in which a very high detection limit is attained, since a nondetection may mask the presence of a chemical at a concentration less than the quantitation limit. Although a quantitative estimate of the chemical's concentration value is unavailable in such a case, the chemical may need to be assessed qualitatively if it is present in other site media

Detection levels also need to be evaluated with respect to ARARs and toxicity screening levels. For some PAHs and dioxins, detection limits below the estimated toxicity effects level for a particular receptor of concern may not be possible. For other chemicals, such as mercury, the detection limit (0.01 pg/L) is barely below the AWQC (0.012 pg/L).

4.2.3.3.2 Chemical Distribution. The physical distribution and frequency of detection of a chemical in a site medium or exposure area can be used to remove a chemical from consideration as a COEC. The premise behind this criterion is that a chemical with limited presence in a medium or exposure area is unlikely to be contacted frequently and, therefore, does not pose as great a potential ecological risk as do more frequently detected chemicals.

The distribution of the chemicals present in a site or exposure area should be examined by identifying where the chemicals were and were not detected and their frequency of detection. If this evaluation indicates that the distribution of a chemical is low, i.e., it is detected in only one or a few locations, it may be reasonable to exclude it as a COEC (assuming an appropriate sampling design was used), or to select the chemical as a COEC for a smaller exposure area of the site. Within the smaller exposure areas, chemicals detected in five percent or fewer samples may also be considered for elimination.

The following factors should be considered when applying this criterion:

- The number of samples available. In a small data set, a limited frequency of detection of a chemical may be more a statistical artifact of a limited sampling design rather that the infrequent presence of the chemical.

- The quantitation limit achieved. If the quantitation limit achieved in one or more of the analyses is high relative to other detected concentrations, the high quantitation limit may mask the presence of chemicals.

- The sampling scheme. Biased sampling plans, intended to identify "hot spots," may over-represent the occurrence of chemicals (however... see the next point).

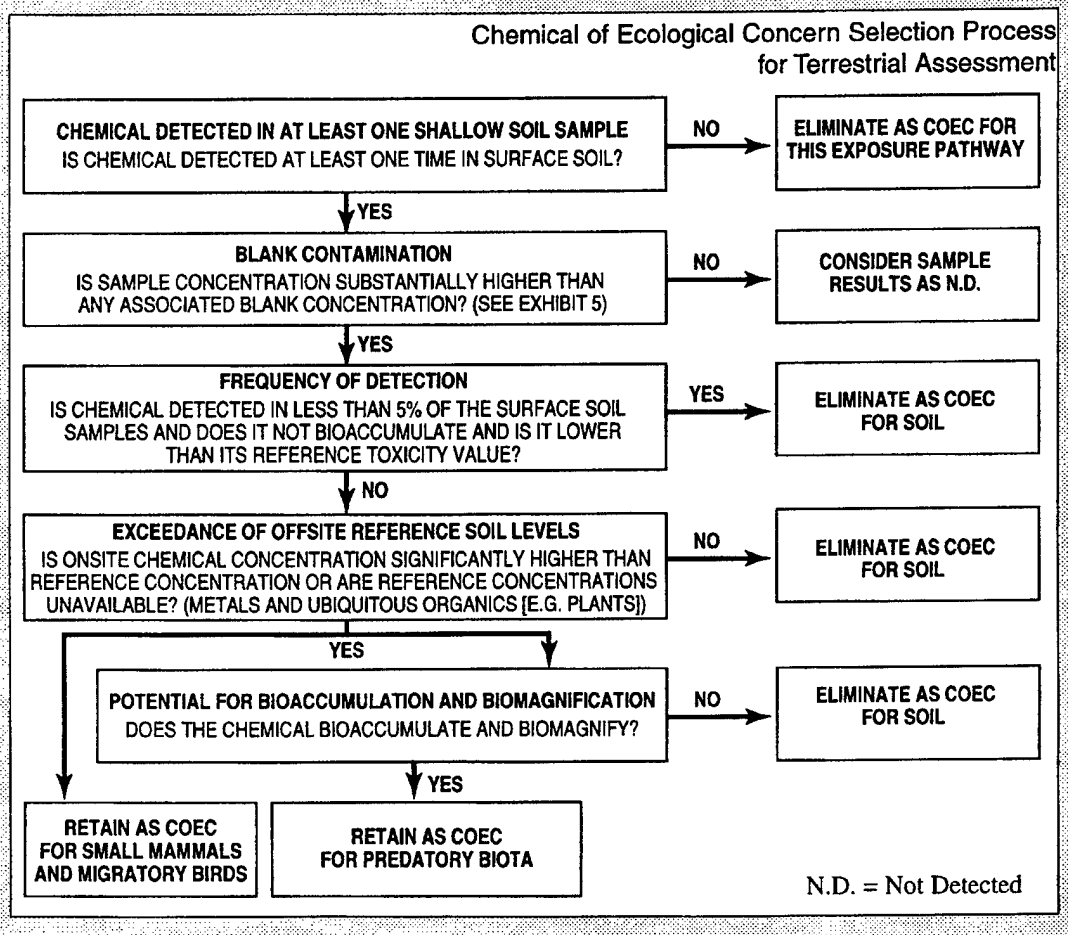
CASE STUDY 6

SELECTION OF COECS - I (TERRESTRIAL ECOSYSTEM)

The chemical data for soil need to be examined to select chemicals of ecological concern, or COECs, for the assessment. Examine the data for soil with respect to the provided information and the following factors:

- Nondetection,
- Comparison with laboratory blanks,
- Limited presence,
- Comparability with background concentrations,
- Non-site-relatedness,
- Role as an essential nutrient,
- Toxicity screen, and
- Potential for bioaccumulation and biomagnification.

Then select the COECs. A flow diagram similar to that shown below may be developed to depict the COEC selection process that is used.



CASE STUDY 7

SELECTION OF COECS - II (TERRESTRIAL ECOSYSTEM)

Now examine the soil data and select soil COECs for the ERA:

Comparison with Laboratory Blanks - Soils

Acetone was detected in several soil samples. There are no field blanks associated with the soil samples, so no direct comparison with field blanks can be made. However, three factors suggest that acetone is not site-related. First, the B qualifier indicates that acetone was detected in the laboratory method blanks and is therefore a laboratory contaminant. Second, acetone was found in background soil samples at concentrations comparable to those in site samples. Third, acetone is volatile and would not be retained in surface soil, suggesting its presence as a laboratory contaminant. For these reasons, acetone is not retained as a COEC (although it is treated as a COEC for the purpose of developing a Reference Toxicity Value [RTV] in CS 12).

Comparison with Background - Soils

A statistical evaluation or a numerical comparison can be used to make background comparisons. In this example, a numerical comparison is used due to the limited number of background samples. Three factors are examined: the range of concentrations detected, the arithmetic mean, and the 95% upper confidence limit (UCL) of the mean concentration (assuming a lognormal distribution). The 95% UCL is calculated only for site data because the background sample size (n = 2) is too small to support statistical estimation of the mean.

	Arsenic	Barium	Cadmium	Nickel	Lead
Site Samples					
Range (mg/kg)	5U-11.4	302-433	2.9-100	12-21	4-19
Arithmetic Mean	6.3	352.6	60.1	17.1	15
95% UCL	10.5	390	81.8	19.2	18
Sample Size	10	10	10	10	10
Background Samples					
Range (mg/kg)	6.2-8.4	376-392	32-56	16-19	13-19
Arithmetic Mean	7.3	384	44	17.5	16
Sample Size	2	2	2	2	2

When ranges of concentrations are compared and mean and 95% UCL site concentrations are compared to background means, arsenic, barium, nickel, and lead appear to be comparable to background; cadmium does not. From this numerical comparison, concentrations of arsenic, nickel, barium, and lead are considered comparable to background concentrations and these metals are therefore not selected as COECs. Cadmium is retained as a COEC for this site.

Examination of Role as Essential Nutrient - Soils

None of the metals detected in surface soils, with the possible exception of arsenic, are essential micronutrients for ecological receptors.

- The concentrations detected. Presence of a chemical at relatively high concentrations, even at a low frequency, may indicate the occurrence of a localized area of contamination (i.e., a hot spot) that may need to be examined as a discrete exposure area, and may require further sampling. What constitutes a "high" or a "low" concentration depends upon the toxicity and other properties of the chemical, the medium in which it was detected, and the site history (whether the chemical was used at the site), and requires some degree of professional judgment to identify.

4.2.3.3.3 Comparability with Background Concentrations. In conducting a risk assessment, it may be important to distinguish site contamination from background levels due to anthropogenic or naturally occurring contamination in order to determine the presence or absence of contamination and to compare with background risk (EPA 1992d,e). Some chemicals detected in site media may be naturally occurring or present as a result of ubiquitous or offsite chemical use. Therefore, it is appropriate to exclude them from the risk assessment. Exhibit 6 presents some chemicals that should be examined for presence in background samples. Background samples are kept discrete from the site data for the purposes of assessing exposures, and are used exclusively to identify non-site-related chemicals.

The most appropriate measure of background quality is obtained by the collection of background data from unaffected onsite areas or nearby, offsite areas, or reference areas. The risk assessor should be involved in the selection of background sample numbers, types, and locations as part of the ERA minimum data requirements, to ensure that adequate data are collected. When selecting COECs, the background data collected should be reviewed to identify whether minimum requirements have been met, or in the case of historical data, whether background measurements are adequate. The following factors should be considered.

Are the locations of the background samples appropriate?

- Appropriate background sampling locations vary with the media being examined, but should generally be offsite; hydrologically upgradient for surface water and sediments: upwind of the site at the time of measurement and under usual climate conditions for air; and in areas remote from surface water drainage for soil. Background samples should also be located away from other potential offsite sources of contamination that would not impact the site, such as other sites, roadways, etc.

- If offsite areas have the potential to contribute chemicals to the site being assessed (for example, upgradient industrial facilities), part of the goal of identifying appropriate background sample locations should be to obtain sufficient background samples to identify potential chemical contributions from offsite sources.

Are the background samples comparable in type to the media being examined?

- Background samples should be as similar as possible to the site samples being evaluated. Background sampling locations should have similar habitat and soil conditions to the onsite locations. Soil and sediment depths and stream characteristics should be comparable. The type of analyses performed on site and background samples (such as filtered versus unfiltered water, soluble versus total metals) should also be comparable.

Are the number of background measurements sufficient?

- Erroneous conclusions may be drawn if the number of background samples collected is insufficient to adequately describe background. The number of background samples should be specified as a minimum requirement during the project planning stage. The actual number of samples with data available should be examined to determine if the minimum requirements have been met. For historical data, professional judgment must be used to determine whether adequate background samples are available, or if additional samples are required.

- Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between sample mean and the 95% UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95% UCL is close to the sample mean) (EPA 1992h). In general, the UCL approaches the true mean as more samples are included in the calculation.

Acquisition of site-specific background information is always preferable to regional or national values when examining site-relatedness and comparability to background concentrations. Literature values describing regional or national background ranges for chemicals in soil, groundwater, surface water, and sediments may be used, but only if site-specific background is unavailable. Regional or national ranges are relatively insensitive and can lead to the erroneous exclusion of a chemical as a COEC. If historical data include NPDES data, they may be used in addition to any other regulatory-required data acquisition.

Determination of comparability with background can be accomplished in several ways, depending on the amount of data available. Two methods that are available are statistical evaluation and numerical comparison.

A statistical evaluation is best when enough site and background samples are available to test the null hypothesis that there is no difference between the site and background mean chemical concentration at a defined level of confidence. This approach can be used when the risk assessor has defined the minimum requirements for background and site sample numbers and sampling design.

Several statistical tests are available with which to determine whether the two data groups, background and site, are comparable. Texts on statistics, such as Zar (1984), Ludwig and Reynolds (1988), or Gilbert (1987), should be consulted for tests applicable for use in specific site conditions. Test selection depends upon data distribution (normal, non-normal), whether nondetected values are included, if appropriate proxy values are used, number of samples, and other factors. This is the most rigorous method of determining comparability. An example of one type of statistical comparison that assumes a normal distribution of data with two unequal variances is shown in CS 8.

Numerical comparisons can be made when background data are more limited in number, making a statistical comparison less meaningful. This approach may be useful when historical data with limited background samples are being used, or when minimum requirements for ERA data collection have not been met and less than optimal numbers of background sample results are available. The following comparisons can be made:

- Comparison of site and background arithmetic mean concentrations.
- Comparison of site and background 95% UCL concentrations.
- Comparison of range of detected concentrations in both data sets.

For the most thorough comparison, all three of these factors should be examined. In a numerical comparison, the definition of "comparability" is arbitrary. Selecting a factor, such as a factor of two, while arbitrary, provides a benchmark against which to define comparability. As an example of this approach, site samples could be defined as comparable if the mean concentration were less than or equal to two times the mean background concentration.

4.2.3.3.4 Determination of Site-Relatedness. Background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of chemicals (EPA 1989f). In some instances, comparison with background is insufficient to identify chemicals that are derived from other sources, despite appropriate planning of background sample locations. If such chemicals are not site-related, however, they generally should not be included in the ERA, although this decision requires professional judgment for reasons noted earlier (Section 4.2.3.3) and policy[3] considerations. If adequate and confirmable information is available that identifies a different site as the source of a chemical, even in the absence of background information, it may be appropriate to exclude that chemical as a COEC. The supporting information must be conclusive and presented in the report.

4.2.3.3.5 Trace Element and Essential Nutrient Status. Some chemicals are essential trace elements or nutrients in the diet of plants or animals, and may be present in site media at nutritionally required concentrations or ecologically protective levels. The following chemicals can be evaluated with regard to essential trace element or nutrient status:

[3] Recent court cases, plus policies adopted by some states, suggest that "non-site-relatedness" is not an appropriate criterion: mere presence of a potential COEC may require a response, while the assessment or assignment of liability for that response must be determined separately and is not to interfere with the response assessment.

CASE STUDY 8

EXAMPLE OF APPLYING A STATISTICAL TEST TO DETERMINE COMPARABILITY WITH BACKGROUND

Data Set:

Site Samples	Background Samples
$x_1 = 125$	$x_2 = 97$
$s_1 = 50.6$	$s_2 = 26.9$
$n_1 = 40$	$n_2 = 8$

Assumptions: If the data for the analyte are normally distributed or can be log-transformed to become normal, the Student's t-test is used. If the data are neither normal nor log-normal, then a nonparametric test such as the Mann-Whitney U test is used.

The distribution of the results suggested that both the site and background data are normally distributed. The population variances are unknown but assumed to be unequal.

Hypothesis: The null hypothesis is

H_0: $\mu_1 \leq \mu_2$

The alternative hypothesis is

H_a: $\mu_1 > \mu_2$

Procedure: The calculations are conducted assuming unequal variances between the two data sets. This assumption generally holds true for environmental data sets but will not impact the results if the variances are equal. The test results include a calculated t parameter and degrees of freedom (df). The calculated t is compared to the critical t (assuming a significance level of a = 0.01) to assess if the null hypothesis is rejected. The nondetects may be treated as follows: (1) for those data sets with more than 85 percent of detects, the nondetects are replaced by 1/2 of the SQL, and (2) for those data sets with 30 to 85 percent detects, Aichison's Adjustment may be performed before the t parameter is calculated to account for the nondetects in the data sets. The Aichison's adjustment procedure is explained in greater detail in the *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities* (EPA 1989g). If 30 percent or fewer of the samples have detectable concentrations, then tests such as the Poisson Tolerance Limits (PTL) are used.

Statistic:

$$t = \frac{(x_1 - x_2) - (\mu_1 - \mu_2)}{(s_p^2/n_1 + s_p^2/n_2)^{0.5}}$$

x = mean concentration of the sample set (mg/kg)
s = standard deviation (mg/kg)
n = sample size
μ = true mean of the population
s_p^2 = pooled sample variance

Using this method, the sample variances are pooled by the following equation:

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

$$s_p^2 = \frac{(40 - 1)(50.6)^2 + (8 - 1)(26.9)^2}{40 + 8 - 2}$$

$$s_p^2 = 2,281$$

Distribution of Test Statistic: If the null hypothesis is true, the test statistic follows the Student's t distribution with v' degrees of freedom.

$$v' = \frac{\left[\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}\right]^2}{\frac{(s_1^2/n_1)^2}{n_1 - 1} + \frac{(s_2^2/n_2)^2}{n_1 - 2}} = \frac{\left[\frac{(50.6)^2}{40} + \frac{(26.9)^2}{8}\right]}{\frac{(50.6^2/40)^2}{40 - 1} + \frac{(26.9^2/8)^2}{8 - 1}}$$

v' = the adjusted degrees of freedom and the standard t distribution table can be used.

$$s_p^2 = \frac{\sqrt{s^2}(n_1 + n_2)}{n_1 + n_2}$$

Decision Rule: Fail to reject (accept) the null hypothesis if $t > 1.684$.

Accept (or fail to reject) the alternative hypothesis if t does not exceed 1.684.

Calculation:

$$t = \frac{(125 - 97) - (0)}{\left[\frac{2281}{40} + \frac{2281}{8}\right]^{\frac{1}{2}}} = 1.51$$

Decision: The calculated t value does not exceed 1.684. Therefore the null hypothesis must be rejected, and the alternative hypothesis is not rejected (i .e., that site concentrations exceed background concentrations).

- Calcium.
- Copper.
- . Chromium (trivalent).
- . Magnesium.
- [illegible]
- Iron.
- Potassium.
- Selenium.
- Sodium.
- [illegible]

Elements that serve as nutrients and are within the recommended allowable dietary range for some receptors may be toxic to other ecological receptors at the same concentration (McDowell 1992). For example, metals such as copper may not be toxic to animals which drink the water, but may be toxic to aquatic organisms. The toxicity of such chemicals should be evaluated in light of the potential site-specific receptors. As a general screening tool, the nutritional requirements of domestic animals (mammals and birds) can be used to assess whether site concentrations of these elements are within acceptable ranges or are likely to pose a hazard to onsite receptors. Nutritional requirements and limits for livestock and experimental laboratory animals (e.g., small mammals, birds, fish) are well-established.

The evaluation of chemicals as trace elements or dietary requirements may be made on a qualitative or quantitative basis. Elements such as calcium, iron, magnesium, potassium, and sodium are rarely retained as COECs, for example. It should be noted in any case, however, whether the elements could be present at a site as a result of site activities. If it is known that a particular element's occurrence is a result of site activities, it may not be appropriate to remove it from the list of COECs.

4.2.3.3.6 Preliminary Toxicity Screen

A toxicity screen to determine which chemical concentrations exceed applicable regulatory standards (toxicity benchmarks) is performed for the selection of COECs. Various reference toxicity values for water and sediment developed by EPA (1986b, 1993b, 1994e, 1995b,f) can be used. ORNL (1994) has also developed screening benchmark preliminary values for aquatic and terrestrial ecosystems.[4] Guidance values from NOAA (Long and Morgan 1990), Washington State Department of Ecology (1991) Florida Dept. of Environmental Protection (MacDonald 1994), and Canada (Long et al. 1995, Persaud, Jangumagi, and Hayton 1992, CCME 1995) for marine and freshwater sediment threshold environmental effects levels can be used directly in Tier I screening for COECs in aquatic ecosystems with few or no modifications (see Exhibit 7). Additional toxicity benchmarks for aquatic ecosystems may be developed using information provided in EPA databases such as ECOTOX and ASTER (see Appendix B, Information Sources).

Standardized values to perform a toxicity screen of chemicals in terrestrial ecosystems are generally not available, although ORNL (1994) has recently published toxicity benchmarks for a variety of benchmarks that can be used in a Tier I terrestrial toxicity screen. Standardized values for screening terrestrial wildlife are currently under development by EPA. Four water quality criteria (mercury, p,p'-dichlorodiphenyl-trichloroethane [DDT], 2,3,7,8-tetrachlordibenzo-p-dioxin [TCDD], and polychlorinated biphenyls [PCBs]) for the protection of wildlife (birds and mammals) which feed on aquatic organisms are published in the GLWQI Final Rule (EPA 1995b). In a few cases, chronic Federal AWQC for chemicals that bioaccumulate are based on final residue values and the protection of sensitive mammals (PCBs and mink) or birds (DDT and brown pelican). Where such exposure pathways are appropriate, the GLWQI criteria and Federal and state AWQC should be used in screening water concentrations for COEC selection. A cautious approach should be used in COEC screening as toxicity can differ among similar receptor species due to differences in either physiology or exposure. For example, some songbirds seem to be more sensitive to organophosphorus compounds than other songbirds (personal communication, Dr. J. Whaley, USACHPPM, 1995).

---

[4] The ORNL (1994) benchmark values are a useful preliminary screening tool. However, these documents do contain errors, have yet to be widely peer-reviewed, and should not be considered standardized benchmarks. ORNL will be updating these benchmarks and posting them on the Internet (www.ornl.gov).

In terrestrial ecosystems, chemicals may be very limited in distribution, but still present potential for acute toxicity for ecological receptors. For those chemicals that are found at limited locations or in 5 percent or fewer samples and tend not to bioaccumulate, the lethal concentration for 50 percent of the population (LC_{50}) values (for plants or soil-dwelling organisms) may be compiled from available ecotoxicological literature and compared to the 95th UCL concentration in soil. The concentration term for each chemical in soil is the lower of (1) the maximum detected concentration or (2) the 95% UCL of the mean (see Section 4.3.3).

Chemicals that have the potential to bioaccumulate or biomagnify through the food web should be retained for consideration as COECs, even where distribution is limited or they might be eliminated based on the preliminary toxicity screen. Chemicals that bioaccumulate include those that are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemicals (Rand and Petrocelli 1985). Chemicals that biomagnify are those that are found in increasingly higher tissues concentrations in higher trophic levels (i.e., concentrations increase across at least two trophic levels) (EPA 1995b). By definition, chemicals that tend to biomagnify also bioaccumulate. Chemicals with a log K_{ow} of less than 3.0 or a K_{oc} of less than 500 (i.e., log K_{oc} less than 2.7) are not expected to bioaccumulate or biomagnify. A lengthy list of bioaccumulative (biomagnify) and nonbioaccumulative chemicals that are of potential concern is presented in the GLWQI (EPA 1995b)[5] (see Table 4-1).

The chlorinated pesticides are the most well known of the chemical groups that tend to bioaccumulate and biomagnify. PCBs and dioxins/furans are also strong bioaccumulators and biomagnifiers. Volatile organic compounds (VOCs) such as tetrachloroethene, toluene, trichloroethene, 1,1,1-trichloroethane, and xylenes are unlikely to bioaccumulate and biomagnify (Van Leeuwen et al. 1992; EPA 1982). Semivolatiles, including PAHs, tend not to bioaccumulate and show little tendency to biomagnify because they are readily metabolized (Eisler 1987, Beyer and Stafford 1993).

4.2.3.4 Presentation of Chemicals of Ecological Concern

The chemical selection process results in a select list of preliminary COECs that will be quantitatively assessed in the ERA. Tables should be developed identifying the COECs selected for each medium and/or exposure area. All chemicals that were removed from consideration should be identified, with an explanation of the reason for the removal. A flow diagram illustrating the COEC selection process should be included to clearly illustrate the decision process used (CS 6).

4.2.4 Selection of Key Receptors

Receptors are the components of ecosystems that are or may be adversely affected by a chemical or other stressor. Endpoints are characteristics of an ecological component that may be affected by an environmental stressor (e.g., chemical contaminant) (EPA 1992a). Because it is difficult to assess potential impacts to all receptors for all endpoints, ecological assessment methods select particular types of receptors (key receptors) and endpoints (see Section 4.2.5) to represent potential harm to all components of the system.

4.2.4.1 Objectives

Grouping of species, organisms, habitats, or ecosystem components under the heading of key receptors helps focus the exposure characterization portion of the Tier I ERA on species or components that are the most likely to be affected and on those that, if affected, are most likely to produce greater effects in the onsite ecosystem. The focus of the receptor selection process is on species, groups of species (e.g., birds, benthic invertebrates), or functional groups (feeding guilds), rather than higher organizational levels such as communities or ecosystems. Chemical-specific toxicological input parameters are also generally limited to the more common organisms or species in the onsite environment and prey organisms that are likely to be used more heavily than others. Although grouping species together for the purposes of exposure and risk quantitation (model analysis) results in some error of uncertainty, this error might be offset by the use

[5] The GLWQI table is based on chemicals that bioaccumulate and are of initial concern in the Great Lakes because of their strong tendency to biomagnify. Chemicals listed in this table as "'not of concern" are still of considerable concern due to their bioaccumulation potential. Chemicals that bioaccumulate in lower level organisms may still present a significant contaminant pathway and dietary hazard to higher trophic level receptors, even if they don't biomagnify in the latter. For example, copper is bioaccumulated to very high level by oysters, but does not biomagnify through food webs. PAHs are accumulated in invertebrates which lack metabolic pathways for their excretion, yet am not accumulated in most vertebrates which have such enzyme systems.

Table 4-I
Chemicals of Ecological Concern According to Final Water Quality Guidance for the Great Lakes System (EPA 1995b)

Pollutanta that an bioaccumulative chemical of concern (BCCs)
Chlordane
p,p'-dichlorodiphenyl-trichloroethane (DDT) and metabolites
4,4'-DDD; p,p'-DDD; 4,4'-TDE; p,p'-TDE
4,4'-DDE; p,p'-DDE
4,4'-DDT; p,p'-DDT
Dieldrin
Hexachlorobenzene
Hexachlorobutadiene; hexachloro-1,3-butadiene
Hexachlorocyclohexanes (HCH); BHCs (benzene hexachloride; synonym for HCH)
alpha-Hexachlorocyclohexane
beta-Hexachlorocyclohexane
delta-Hexachlorocyclohexane
Lindane; gamma-BHC; gamma-hexachlorocyclohexane
Mercury
Methoxychlor
Mirex; dechlorane
Octachlorostyrene
PCBs; polychlorinated biphenyls
Pentachlorobenzene
Photomirex
2,3,7,8-TCDD; dioxin
1,2,3,4-Tetrachlorobenzene
1,2,4,5-Tetrachlorobenzene
Toxaphene
Pollutants that are not bioaccumulative chemicals of concern*
Acenaphthene
Acenaphthylene
Acrolein; 2-propenal
Acrylonitrile
Al&in
Aluminum
Anthracene
Antimony
Arsenic
Asbestos
1,2-Benzanthracene; benz[a]anthracene
Benzene
Benzidine
Benzo[a]pyrene; 3,4-benzopyrene
3,4-Benzofluoranthene; benzo[b]fluoranthene
11,12-Benzofluoranthene; benzo[k]fluoranthene
1,2-Benzoperylene; benro[ghi)perylene
Beryllium
Bis(2-chloroethoxy)methane
Bis(2-chloroethyl) ether
Bis(2-chloroisopropyl) ether
Bromoform; tribromomethane
4-Bromophenyl phenyl ether
Butyl benzyl phthalate
Cadmium

Table 4-1 (Continued)

Pollutants that are not bioaccumulative chemicals of concern*

Carbon tetrachloride; tetrachloromethane
Chlorobenzene
p-Chloro-m-cresol; 4-chloro-3-methylphenol
Chlorodibromomethane
Chloroethane
P-Chloroethyl vinyl ether
Chloroform; trichloromethane
P-Chloronaphthalene
2-Chlorophenol
4-Chlorophenol phenyl ether
Chlorpyrifos
Chromium
Chrysene
Copper
Cyanide
2,4-D; 2,4-Dichlorophenoxyacetic acid
DEHP; di(2-ethylhexyl) phthalate
Diazinon
1,2:5,6-Dibenzanthracene; dibenz[a,h)anihracene
Dibutyl phthalate; di-n-butyl phthalate
1,2-Dichlorobenzene
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3'-Dichlorobenzidine
Dichlorobromomethan; bromodichloromethane
1,1-Dichloroethane
1,2-Dichloroethane
1,1-Dichloroethylene; vinylidene chloride
1,2-trans-Dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene; 1,3-dichloropropylene
Diethyl phthalate
2,4-Dimethylphenol; 2.4-xylenol
Dimethyl phthalate
4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioctyl phthalate; di-n-octyl phthalate
1,2-Diphenylhydrazine
Endosulfan; thiodan
alpha-Endosulfan
beta-Endosulfan
Endosulfan sulfate
Endrin
Endrin aldehyde
Ethylbenzene
Fluoranthene
Fluorene; 9H-fluorene
Fluoride
Guthion
Heptachlor

Table 4-1 (Concluded)

Pollutants that are not bioaccumulative chemicals of concern*

Heptachlor epoxide
Hexachlorocyclopentadiene
Hexachloroethane
Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene
Iron
Isophorone
Lead
Malathion
Methoxychlor
Methyl bromide; bromomethane
Methyl chloride; chloromethane
Methylene chloride; dichloromethane
Naphthalene
Nickel
Nitrobenzene
2-Nitrophenol
4-Nitrophenol
N-Nitrosodimethylamine
N-Nitrosodiphenylamine
N-Nitrosodipropylamine; N-nitrosodi-n-propylamine
Parathion
Pentachlorophenol
Phenanthrene
Phenol
Pyrene
Selenium
Silver
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Thallium
Toluene; methylbenzene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene; trichloroethene
2,4,6-Trichlorophenol
Vinyl chloride; chloroethylene; chloroethene
Zinc

Source: EPA. 1995b. Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors. Final Rule. Federal Register. Vol. 60. No. 56. March 23.

* Pollutants that are not bioaccumulative (or biomagnifying) chemicals of concern may still be COECs.

of conservative criteria to select key receptors with the greatest sensitivity (highest trophic level receptor or chemically sensitive) or greatest opportunity for exposure.

4.2.4.2 General Considerations

The selection of key receptors is in part a subjective decision based on species presence, dominance, judged importance in the food chain, and societal or scientific value. Key receptors and assessment endpoints are not only species, but may include habitat or areas of special legal protection. Location-specific ARARs, identified as part of the RI effort, may concern locations of natural resources, sensitive ecological receptors, or species protected under a number of resource protection statutes. Some of these statutes were developed several decades ago, and their requirements are very specific. A list of these statutes and the ecological receptors they are designed to protect is presented in Table 4-2. Environmental statutes such as the ESA, Migratory Bird Treaty Act, Eagle Protection Act, and Wetlands Protection Act are used in conjunction with other criteria to help identify (but not mandate) important receptors and select appropriate ecological endpoints (see Exhibit 8). These laws may also be applied to risk management decision-making during the FS/CMS to evaluate the need for and extent of remediation and the potential effects of various remedial alternatives, based on risk characterization performed in the ERA.

Primary criteria for key receptor selection generally include consideration of the following:

- Likelihood of contacting chemicals.
- A key component of ecosystem structure or function (e.g., importance in the food web, ecological relevance).
- Listing as rare, threatened, or endangered by a governmental organization; or critical habitat for such.
- Sensitivity to chemicals.
- Recreational or commercially valued species (e.g., game and livestock).

Additional criteria used in key receptor selection include habitat preference, food preference, and other behavioral characteristics which can determine population size and distribution in an area or significantly affect exposure potential. Key receptors may include mobile game species with large home ranges: or smaller nonmigratory species; or organisms that are sedentary or have a more restricted movement. For chemicals that bioaccumulate, the effects are usually most severe for organisms at the top of the food chain (e.g., top predators) like bass in aquatic ecosystems or raptors in terrestrial ecosystems.

4.2.4.2.1 Likelihood of Contacting Chemicals. Data from the site reconnaissance, biota checklist (if available), and other available literature are used to compile a candidate list from which preliminary key receptors are selected. General field guides and publications on local and regional fauna, including environmental impact statements, provide good preliminary information. Regional natural resource agencies, such as state fish and wildlife departments, should be consulted for more detailed information. Site maps should be reviewed for information on general physiography, ecosystems, and habitat types.

Potential key receptors should be evaluated with respect to their likelihood for directly or indirectly contacting areas affected by chemical input. Key receptor selection analysis includes an evaluation of the receptor's relation to potential COEC exposure through both direct contaminant accumulation from the abiotic environment and bioaccumulation through the food chain. Habitat destruction and loss or absence of the receptor from impacted habitats are additional considerations in selecting key receptors.

Where sites are large and numerous species are likely to be present, the preliminary receptors may be reduced into categories (e.g., small birds, small mammals, wading birds, semiaquatic mammals) or into groups of species that are more toxicologically sensitive (i.e., demonstrate adverse effects to lower environmental concentrations of the COECs). The list may also be reduced by grouping species into taxonomically related groups and/or feeding guilds, such as hawks or eagles that are often top predators in terrestrial food webs. From the reduced list, representative species can be determined on the basis of observations indicating which species are common onsite and potentially most sensitive to the COECs.

4.2.4.2.2 Sensitivity to Chemicals. Species differ in the ways that they take in, accumulate, metabolize, distribute, and excrete contaminants. Susceptibility of an organism also varies with the manner in which organisms am exposed to chemicals in their environment. When possible, key receptors and endpoints arc selected by identifying those that are known to be susceptible to chemicals at the site based on published literature This process

Table 4-2
List of Environmental Laws and Ecological Receptors (Adopted from the revised Hazard Ranking System (rHRS), 55 FR 51624, December 14,1990)

Ecological Receptors to be Protected	Statutory/Regulatory References
Critical habitat for Federal designated endangered or threatened species	Critical habitat as defined in 50 **CFR** 424.02; The Endangered Species Act Amendments of 1978
Marine Sanctuary	Marine Mammal Protection Act of 1972; Marine Protection, Research, and Sanctuary Act of 1972
National Park	National Park and Recreation Act of 1978
Designated Federal Wilderness Area	Endangered American Wilderness Act of 1978
Areas identified under Coastal Zone Management Act	Areas identified in State Coastal Zone Management plans as requiring protection because of ecological value; Coastal Zone Management Act Amendments of 1976
Sensitive Areas identified under National Estuary Program or Near Coastal Waters Program	National Estuary Program study areas (subareas within estuaries) identified in Comprehensive Conservation and Management Plans as requiring protection because they support critical life stages of key estuaries species under Section 320 of the Clean Water Act; near Coastal Waters as defined in Section 104(b)(3), 304(1), 319, and 320 of the Clean Water Act of 1977
Critical areas identified under the Clean Lakes Program	Clean Lakes Program critical areas (subareas within lakes, or in some cases entire small lakes) identified by State Clean Lake Plans as critical habitat (Section 314 of the Clean Water Act of 1977)
National Monument	Use only for migration pathway
National Seashore Recreational Areas	
National or State Wildlife Refuge	National Wildlife Refuge System Administration Act of 1966
Unit of Coastal Barrier Resource System	
Coastal Barrier (undeveloped)	
Federal land designated for natural ecosystems	National Forest Management Act of 1976
Administratively Proposed Federal Wilderness Area	
Spawning areas critical for the maintenance of fish/shellfish species within river, lake, or coastal tidal waters; Fishery Conservation and Management Act of 1976;	Limited to areas described as being used for intense or concentrated spawning by a given species
Migratory pathways and feeding areas critical for maintenance of anadromous fish species within river reaches or areas in lakes or coastal tidal waters in which fish spend extended periods of time	Anadromous Fish Conservation Act of 1965
Terrestrial areas utilized for breeding by large or dense aggregations of animals	For the air migration pathway, limited to terrestrial vertebrate species. For the surface water migration pathway, limited to terrestrial vertebrate species with aquatic or semiaquatic foraging habitats; Tule Elk Preservation Act of 1965;
National river reach designated as recreational	National Wild and Scenic River System of 1968
Bald and Golden Eagle	Bald Eagle Act of 1940

ensures that a conservative approach is taken to evaluate receptors (at the individual/population, community, or ecosystem level) and endpoints likely to be adversely affected in combination with the potentially most hazardous chemicals found at the site.

4.2.4.2.3 **Threatened and Endangered Species.** By definition, endangered and threatened species are already at risk of extinction; the loss of only a few individuals from the population may have significant consequences for the continued existence of the species. While threatened and endangered species and/or habitats critical to their survival may not necessarily be an important functional component of the ecosystem, they are generally selected as key receptors due to their significant social and scientific value. If a species is rare, but not legally designated as either threatened or endangered, local ecologists or other experts should be consulted to determine the importance of the species in the context of the site. Migratory birds may also require special consideration (see Exhibit 8).

Federal and state natural resource trustees or other specialists should be consulted to determine the location of such species and their potential for exposure to the COECs. The major sources of information on rare, threatened, and endangered species are field offices of the USFWS and NOAA, officials of state fish and game departments and natural heritage programs, and local conservation officials and private organizations.

4.2.4.2.4 **Importance of the Food Web. The** putpose of determining the food web is to evaluate pathways from chemicals in soil, sediment, or water to the affected species. Food web analysis is most important where toxicological data indicate that the COECs bioaccumulate or if the direct effects on organisms from COECs might alter population levels of one or more species. Food webs for many sites can be quite complex. Diagramming the complete food web, however, is rarely reasonable nor necessary. Based on the preliminary list of important species at the site, a preliminary simplified food web can be drawn (see **Section 4.2.6).**

4.2.4.2.5 Food Web Construction. Food web construction requires general knowledge on the food habits of species or species groups (e.g., waterfowl, grasshoppers, zooplankton) potentially occurring on the site. Available data on feeding relationships, such as the percent contribution of a prey species in the diet of a predator, can be included to indicate the strength of the feeding relationship.

Depending on the particular site conditions, one may construct either one or more simple food chains, a community food web, a sink food web, or a source food web (Fordham and Reagan 1991). A food chain would be used to illustrate the movement of chemicals through a series of organisms by progressive consumption. A community food web includes the feeding relations of the entire community. A source food web includes a designated food source (e.g., a particular plant species), all of the organisms that consume the source, and all the species that consume these organisms up to the highest trophic levels involved (Cohen 1978). A sink food web is also a subset of the community food web and includes all the types of organisms eaten by a designated sink species (e.g., bald eagle), the food of these organisms (e.g., fish and small mammals), and so on to the lowest level of the food web (e.g., primary producers) (Cohen 1978). Sink food webs are especially important where threatened and endangered species are a designated key receptor and the pathways by which chemicals biomagnify through various trophic levels to this receptor are to be quantified.

4.2.4.2.6 Keystone Species. Species that may not appear to be important may nevertheless play significant roles in the stability of an ecosystem. Certain rodents (kangaroo rats, prairie dogs) in the arid southwest, for example, are considered keystone species due to their importance as prey for predators, their practice of managing vegetation in such a way as to control species presence, and their importance in providing habitat for other species like burrowing owls. Certain insect groups (both aquatic and terrestrial) may also be regarded as keystone species because of their importance as prey for a wide variety of receptors, the profound effects they can have on vegetative communities, and their potential importance as vectors for contaminant transport. Because of the specialized knowledge required to recognize keystone species and other important receptors, ecologists play a central role throughout the design and conduct of the ERA.

4.2.4.2.7 Reptiles and Amphibians. The selection of reptiles and amphibians as key receptors should be considered, particularly for installations where there are state or Federally protected species. Consideration of reptiles and amphibians has generally been avoided in ERAs due to limited knowledge about contaminant effects on these taxa. Information on contaminant toxicity and population modeling techniques, particularly for frogs and turtles, however, is becoming more prevalent in the published literature and accessible databases. USACHPPM is currently doing extensive exposure and toxicity modeling for

amphibians.[6] Where scope is limited in an ERA, EPA (1986c) suggests one means for evaluating reptiles and amphibians is to assume that when birds and mammals are protected via the risk criteria of the assessment, then reptiles and amphibians are also protected. While some protection is afforded reptiles and amphibians by these same criteria, the level of protection is not known. As more toxicological information becomes available on such organisms, it should be considered more accurately in the ERA.

Reptiles and amphibians should not be ignored in constructing food webs, particularly where chemicals are known to bioaccumulate. Amphibians and reptiles may carry substantial organochlorine residue burdens due to life history factors, particularly feeding habits. Toads, for example, feed primarily upon insects and other invertebrates, while garter snakes use mainly earthworms, salamanders, toads, and mice (Jorschgen 1970). Amphibians and reptiles in turn are a vital dietary component for a highly visible ecosystem component, the raptors (Ross 1989). Snapping turtles were selected as a key receptor in both the ERA and Human Health Risk Assessments at Aberdeen Proving Ground, Maryland.

4.2.4.2.8 Recreationally and Commercially Valued Species. EPA (1989a) suggests that potential adverse effects be noted on species that are of recreational and commercial importance (e.g., sport fish, game), although as key receptors they may not be ecologically relevant. Species that are food sources and directly support these important species, as well as habitats essential for their reproduction and survival, should also be considered in the planning and assessment process.

Information on which species are of recreational or commercial importance in an area can be gathered from state environmental or fish and wildlife agencies, Federal agencies such as NOAA, USFWS, USFS, and local conservation and fish and game personnel. Commercial fishermen's and trappers' associations may also be valuable sources of data.

[6] Mr. Mark Johnson at USACHPPM is specifically conducting research on the effects of munitions on salamanders. He may be contacted at (410)-671-5081 for further information. Mr. Keith Williams at (410)-671-2953 and Mr. John Paul at (410)-6714567, also of USACHPPM, may be contacted regarding their research on munitions and snapping turtles at Aberdeen Proving Ground.

4.2.5 Ecological Endpoints Identification

Ecological endpoints are identified within the ERA process to provide a basis for characterizing risks to the environment. Ecological endpoints are the particular types of actual or potential impacts a chemical or other environmental stressor has on an ecological component (typically a key receptor). These endpoints are of two types:

- Assessment Endpoints. Explicit expressions of the environmental values that are to be protected (EPA 1992a).
- Measurement Endpoints. Measurable responses related to the valued characteristics chosen as assessment endpoints (EPA 1992a).

ERAs typically address both assessment and measurement endpoints. Assessment endpoints are the ultimate focus in risk characterization and the link to the risk management process (EPA 1992a). Assessment endpoints most often describe the environmental effects that drive decision-making, such as reduction of key populations or disruption of biological community structure (EPA 1989a).

Selected assessment endpoints should focus on identifiable harm that may come to exposed receptors. Such harm includes death or reproductive impairment. Appropriate measurement endpoints should also focus on determining which pathways may be complete for site COECs and receptors. As in the PA/SI, measurement endpoints in the Tier I ERA are frequently based on toxicity values from the available literature. In higher tiers, measurement endpoints are more often expressed as the statistical or arithmetic summaries of the actual field or laboratory observations or measurements (EPA 1992a).

When possible, receptors and endpoints are concurrently selected by identifying those that are known to be adversely affected by chemicals at the site based on published literature. COECs for those receptors and endpoints are identified by &awing on the scientific literature to obtain information on potential toxic effects of site chemicals to site species. This process ensures that a conservative approach is taken to selecting endpoints and evaluating receptors that are likely to be adversely affected by the potentially most toxic chemicals at the site.

4.2.5.1 Assessment Endpoints

Most ecological assessment methods focus on population measures as endpoints, since population responses are more well-defined and predictable than are community and ecosystem responses. The latter responses are often more difficult to measure and interpret, highly variable, and not diagnostic of actual exposure. Population measures can also be used to model changes at the community or ecosystem level. Where the population is protected and individuals are important to the overall sustained success of the population, then assessment endpoints focus on adverse effects at the individual level.

Assessment endpoints are identified by drawing on the scientific literature to obtain information on the potential adverse effects of site conditions to populations, communities, and ecosystem levels of ecological organization. Valued ecological resources such as trees, fish, birds, and mammal populations are typically selected as the focus of the assessment endpoints. In ERAs, ecological entities that are valued (based on a combination of societal and ecological concerns) and to be protected are first identified and then investigated by directly measuring appropriate ecological parameters or responses (measurement endpoints) that are related to the assessment endpoints.[7] Unlike human health risk assessments which focus on risk to individuals, ecological risk assessments usually address risk at the population, community, or ecosystem level of organization. The exception to this is in the case of endangered or threatened species, where individuals must be protected in order to preserve the population.

4.2.5.2 Population Versus Individual/Community/ Ecosystem Endpoints

The toxicity of contaminants to individual organisms (receptors) can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by contaminants, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Potential endpoints for ERAs at the individual, population, community, and ecosystem level include the following (EPA 1989c):

. Level 1: Individual Endpoints:

- Changes in behavior
- Decreased growth
- Death

• Level 2: Population Endpoints:

- Increased mortality rate
- Decreased growth rate
- Decreased fecundity
- Undesirable change in age/size class structure

• Level 3: Community Endpoints

- Decreased species diversity
- Decreased food web diversity
- Decreased productivity
- Change to less desirable community

• Level 4: Ecosystem Endpoints

- Decreased diversity of communities
- Altered nutrient cycling
- Decreased resilience
- Altered productive capability

Population-level assessment endpoints are generally recognized in ERAs because: (1) responses at lower levels (i.e., organismal and suborganismal) may be perceived as

[7] For a site where there are storage yard drums leaking to a nearby stream in which there are fish upon which bald eagles (a Federally protected species) are feeding, a likely assessment endpoint would be: impairment of reproductive success in the bald eagle. The corresponding measurement endpoint could be dose-response data for the COEC in a related species (e.g., another member of the order Falconiformes or family Accipitridae). Exposure characterization could require fish and abiotic media sampling to confirm the contaminant transport pathway and modeling of fish tissue concentrations to bald eagle tissue concentrations. Comparison of dietary (fish) eagle concentrations and modeled eagle tissue concentrations to concentrations known to impair reproduction in the eagle generates the risk estimate.

having less social or biological significance (actions may be taken to protect individuals of endangered species but only because it is prudent in light of the precarious state of the population); (2) populations of many organisms have economic, recreational, aesthetic, and biological significance that is easily appreciated by the public; and (3) population responses are well-defined and more predictable with available data and methods than are community and ecosystem responses (EPA 1989a). Populations are biologically relevant because of their role in maintaining biological diversity, ecological integrity, and productivity in ecosystems: individuals are important only in maintaining populations. Because the environmental values to be protected are sustainability of species or characteristics at higher levels of ecological organization (e.g., biological diversity), the individual level is not appropriate for assessment endpoints evaluation, except where loss of one individual could impact the survival of a threatened or endangered population.

Ecosystem responses are characterized by many of the same measures as communities: species composition and diversity, nutrient and energy flows and rates of production, consumption, and decomposition. Unlike community measures, ecosystem structure and function include nonliving stores of materials and energy along with animals, plants, and microbes that make up the biotic portion of the environment.

There is a general consensus among ecologists that results of community and ecosystem studies are complex and highly variable and, therefore, difficult to interpret. One reason for this difficulty is that contaminants exert their effects on communities both directly and indirectly. Direct and indirect toxicity can cause changes in community structure due to differences in sensitivity among species. Indirect effects such as resultant shifts in diversity, productivity, or predator-prey interactions (as the outcome of competition) are extremely difficult to predict or measure.

Indirect effects of chemicals are often cited as justification for testing at higher level of organization (Tiers III and IV). Implementation of such testing, however, tends to be expensive, time-consuming, presents great uncertainty, and may have limited relevance to the risk management decisions. If ecological endpoints are not appropriate and compelling, they will not contribute to decisions regarding site remediation (EPA 1989a).

4.2.5.3 Measurement Endpoints

When assessment endpoints cannot be measured directly, measurement endpoints are selected. Measurement endpoints are those used to approximate, represent, or lead to the assessment endpoint (EPA 1989c). Measurement endpoints should be selected so as to provide insights related to the specific assessment endpoint. In Tier I, reference toxicity values (e.g., LD_{50}, LOAEL, NOAEL) obtained from the scientific literature are used as toxicological endpoints (or surrogate measurement endpoints) for the purpose of risk characterization. Where estimated exposure concentrations far exceed the effects levels, and adverse effects are considered likely, additional confirmatory data may be needed in the decision-making process. For wildlife, confirmatory data may be obtained on a variety of measurement endpoints including chemical analyses of tissue samples from potentially exposed wildlife or their prey, or from observed incidence of disease, reproductive failure, or death (Tier II activities). Several factors should be examined in the selection of measurement endpoints, including: the sensitivity of the receptor; size comparability: diet composition and quantity; home range size; abundance; resident versus migratory species; and whether toxicity data are available (Hull and Suter 1993). Use of field measurement endpoints may also require comparison to a reference area. Where biological data are to be collected (a Tier II, III, or IV effort), the DQO process and guidance provided in the HTBW Tech*nical Project Planning* document (USACE 1995b) should be followed.

4.2.6 Ecological Conceptual Site Model

The ECSM is a representation, often pictorial, of certain portions of the exposure characterization (CS 3). The ECSM traces the contaminant pathways through both abiotic components of the environment and biotic, food web components of the system (see CS 9). The ECSM, which may have been established in the PA/SI or RFA project phase, presents all potential exposure pathways (sources and release mechanisms, transport media, exposure points, exposure routes and receptors) and identifies those pathways which are complete (significant or insignificant) and incomplete. The ECSM helps the project team focus the data collection effort to evaluate significant pathways and address PDs requirements. At this time, data concerning potential existence and locations of

sensitive environments, endangered species, or valued resources should already have been collected.

The ECSM establishes the complete exposure pathways that are to be evaluated in the ERA and the relationship between the measurement and assessment endpoints. The ECSM forms the basic decision tool for evaluating the appropriateness and usefulness of the selected measurement endpoints in evaluating the assessment endpoints. The ECSM is also used as a tool for identifying sources of uncertainty in the exposure characterization (exposure point chemical concentrations).

Initial formulation of the ECSM in the screening ERA is based upon existing information and assumptions regarding chemical presence and migration, which now should be verified and refined with data collected during the Tier I site investigation. Exhibit 9 discusses the components of the ECSM and identifies some specific factors that should be re-examined as part of the exposure characterization (also see CS 10). Exhibit 10 discusses the role of chemical and physical properties in developing an ECSM.

The ECSM is refined in greater detail throughout the Exposure Characterization portion of the ERA. The risk assessor and project team members should review site data and information collected in earlier project efforts (PA/SI or RFA) to establish or refine the ECSM (based on more complete background information or nonchemical data) and assess potential early/immediate response actions, as appropriate. All existing data should be reviewed for quality, useability, and uncertainty before defining new data acquisition requirements. The information should be able to assist the risk assessor in developing a more definitive ECSM, or multiple ECSMs if there are multiple OUs, SWMUs, AOCs, or CAMUs/TUs (if appropriate). This information should include:

- COECs (information concerning the source characteristics, medium contamination, and background chemicals, including those of anthropogenic origin, is needed to identify COECs).
- Potential target media (groundwater, surface water, soil/sediment, and air).
- Media parameters and characteristics.
- Potential receptors in the target media.
- Major exposure routes or pathways of concern (e.g., direct contact resulting in soil or sediment ingestion or dermal absorption of contaminants in the media, consumption of food chain crops or prey species, surface water ingestion, and inhalation of contaminants in ambient air).
- Migration and transport potential of site chemicals from the source, including the effect of existing institutional controls or interim corrective measures or removal actions (e.g., groundwater capture well systems to prevent migration to surface water).
- Exposure areas or units with common COECs which also pose common exposure pathways and threats to ecological receptors.
- Potential secondary, tertiary, and quatemary sources of contaminants, and their release/transport mechanisms.
- Level of contamination when compared to available ARARs or benchmark values, and relevancy of sample location/matrix.
- Removal actions or interim corrective measures taken.
- Data useability based on quality assurance characteristics, parameter analyzed, validation results, and the way the data were compiled that may severely restrict their use in the risk assessment.

4.3 Analysis Phase - Exposure Characterization

This section discusses the development of the exposure characterization portion of a Tier I ERA. The purpose of the exposure characterization is to estimate the nature, extent, and magnitude of potential exposure of receptors to COECs that are present at or migrating from a site, considering both current and plausible future use of the site. Several components of the exposure characterization have previously been evaluated during earlier stages of the SI and ERA for the purposes of developing the ECSM and focusing investigative activities. These components include identification of COECs, key receptors and food webs, exposure media, and preliminary exposure pathways and areas. These preliminary characterizations were based upon early and often incomplete information that now must be clarified in light of the information obtained during site investigative activities.

The steps required to perform an exposure characterization are:

- Refinement of the preliminary chemical fate and transport model developed during the PA/SI and the preliminary ECSM.
- Characterization of the exposure setting.
- Identification of potential exposure pathways and intake routes.
- Quantitation of exposure.
- Assessment of exposure uncertainties.

Each of the above components is discussed in detail in following sections.

4.3.1 Exposure Setting Characterization

The objective of describing the exposure setting is to identify the site physical features that may influence exposure for both current and future scenarios. While each site will differ in the factors that require consideration, some of the more common factors are listed below and discussed briefly. Examples of how the factors may influence exposure also are provided.

- Geology. The land type and forms may influence exposure in various ways. For example, the topography of the area can influence the direction and rate of movement of chemicals to offsite areas.
- Hydrology. The possible connection of surface water bodies with groundwater should be evaluated where there are surface waters or wetlands. The potential presence of groundwater seeps should also be evaluated. The presence and character of surface water bodies or wetlands may affect potential exposures of aquatic ecosystems.
- Climate. The temperature and precipitation profiles of the area limit the types of receptors present, feeding habits, frequency of exposure (e.g., frozen surface water bodies) as well as influence the extent of chemical migration (e.g., surface water runoff and erosion, infiltration).
- Meteorology. Wind speed and direction influence the entrainment of soil particles and the extent of transport and dilution of air contaminants.
- Vegetation. The nature and extent of vegetation influence the fauna that are present and their potential for exposure through the food chain.
- Soil Type. The type of soil (e.g., grain size, organic carbon, clay content) influences soil entrainment, the degree of chemical binding, leaching potential, bioavailability, and the potential for unique vegetation types to be present. Soil characteristics also influence erosion and the resultant vegetative communities.
- Land Use. The types of receptors likely to have contact with site media and COECs depend, in part, on current and planned future land use. The appropriate current and future land uses should be identified, as is discussed above (see Exhibit 11).

Description of the site setting in the exposure characterization should involve obtaining more specific, in-depth information than was obtained during the preliminary ECSM development. The description should be supplemented by data collected during the site investigation. Description of portions of the exposure setting may have been discussed in other portions of the site report, and need only be referenced in this section. However, characteristics of the exposure setting that are specific to potential exposures should be presented.

4.3.2 Exposure Analysis

Exposure analysis combines the spatial and temporal distributions of the ecological receptors with those of the COECs to evaluate exposure. The exposure analyses focus on the chemical amounts that are bioavailable and the means by which the ecological receptors are exposed. The focus of the analyses depends on the ecological receptors being evaluated and the assessment and measurement endpoints.

4.3.2.1 Exposure Pathways identification

An exposure pathway is the physical course a chemical takes from the source to the exposed receptor (EPA 1989f).

A complete exposure pathway typically consists of the following four elements:

(1) A source and mechanism of chemical release.

(2) A transport medium such as water, soil, or forage (if the exposure point differs from the source).

(3) An exposure point or area where receptors may contact the chemicals.

(4) An exposure (intake) route through which chemical uptake by the receptor occurs (e.g., direct contact, ingestion, inhalation, or dermal absorption).

When all four elements are present, the exposure pathway is considered complete. If one or more of the components are missing (with the possible exception of the second element, transport medium), the exposure pathway is incomplete and there is no exposure and therefore no risk. It should be noted that the exposure point may be at the source itself, or the exposure point may be some distance from the source due to movement of the chemicals through the release and transport mechanisms. Circumstances should also be acknowledged where currently incomplete exposure pathways may present some future risk.'

Exposure pathways should be identified for both current land use and potential future land use, which may or may not be the same. The following factors should be considered when identifying exposure pathways for current and future scenarios:

- **What is the current and future land use?** Land use at and surrounding the site is used to identify the way in which the site is used and the types of exposure pathways that are appropriate. Risk managers and decision makers should be included at this point so that future scenario assessments only include "real world" scenarios and thereby minimize wasted assessment efforts.

- **What is the exposure area?** If relevant, specific portions of the site or offsite areas that may be contacted by potential receptors should be identified. These may be source areas or secondary and tertiary media impacted by the source areas. The plausibility of the entire site being contacted or posing a potential exposure hazard should be examined.

- **In which media are COECs presently contained?** If COECs are not present in a medium sampled during the site investigation, and are not anticipated to be in that medium during the plausible exposure period for current or future receptors, exposure to the medium does not need to be assessed.

- **Into which media are the COECs anticipated to enter within the exposure period for current and future exposure scenarios (for example, accumulation of chemicals into animal and plant species over time)?** Is predictive modeling needed?

- **For what period of time are the COECs expected to remain in the medium?** By examining the chemical's likely fate, it should be determined whether depletion or reduction of the chemical concentration needs to be considered, and whether the exposure pathway is self-limiting.

- **What types of contact with the impacted media are possible?** This determination is based upon uses of the medium and types of contact made with the medium. In general, direct contact (aquatic systems), direct uptake (plants), ingestion (animals), inhalation (animals), and dermal contact (animals) are the possible types of exposure/intake pathways assessed. Inhalation and dermal contact, however, are typically not assessed in terrestrial ERAs as these routes are not well-studied for wildlife. Most wildlife also have protective features such as fur or feathers which result in dermal contact being a negligible exposure pathway for the most part.

Exhibit 12 identifies a generic list of potential exposure pathways and mutes. A brief discussion on pertinent factors for generic exposure routes is presented below. When performing the exposure characterization, these potential exposure routes should each be examined and a decision made regarding the exposure route and pathway completeness of each for the site. Consideration of exposure routes and pathways for aquatic, versus terrestrial receptors requires somewhat different perspectives. Methods for quantifying exposure for these receptors are also

[8] Examples of this include: (1) a contaminated groundwater plume moving toward, but not yet at, discharge points to surface water bodies: (2) sediment contamination buried below the active zone of contamination that may become exposed at some future date due to natural (e.g., hurricane) or anthropogenic causes (e.g., dredging, elimination, or diversion of particulate inputs).

quite different. The approaches for assessing exposure in aquatic and terrestrial receptors are thus presented separately in the following text.

4.3.2.2 Exposure Routes for Aquatic Receptors

As discussed in the preceding section, a complete exposure pathway typically consists of four elements -- a source and release of COECs, a transport medium, an exposure point with receptors, and an exposure (uptake) route. In the aquatic habitat (fresh water, estuarine, or marine), organisms exposed to COECs am principally the aquatic organisms (e.g., algae, plants, invertebrates, fish, marine mammals) or their terrestrial consumers and predators (e.g., shore birds, waterfowl, piscivores). Exposure of terrestrial receptors is discussed in Section 4.3.2.4.

Some common exposure pathways for aquatic receptors are illustrated in CS 3 (aquatic ECSM). The aquatic ECSM serves a very useful purpose -- it enables the risk assessor to visualize where and how COECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The aquatic ECSM also shows which pathways may be significant and what measurement endpoints should be considered.

From the primary source of COECs, chemicals move toward the exposure points via the actions of direct discharge, leaching, infiltration, and erosion. Leaching and infiltration to groundwater is the most common contaminant route to aquatic receptors since many chemical releases are from tanks, pipelines, or other spills to site soils and from there to groundwater. Groundwater itself is only rarely an exposure medium for aquatic receptors, but it is a primary pathway to surface water, where chemical concentrations are rapidly diluted, and to sediment. Volatilization of organic COECs and dust generation from the primary source can occasionally be release mechanisms through the air to water and sediment, but the air pathway is rarely quantifiable except in cases of emissions from stacks or cooling towers.

Once in surface waters, chemicals are affected by a wide variety of physical and chemical processes that can change their chemical configuration, physical location, bioavailability, and toxicity within the aquatic environment. Chemicals can be lost from the water through volatilization. Chemicals in water can move into the bottom or suspended sediments via sorption or complexation with sediments or through precipitation and settling, which can be caused by an increase in the pH of the water. As indicated in the aquatic ECSM, chemicals move between water and sediment, with the sediments often serving as a source of chemicals that have been sequestered from past releases of COECs. Sediments are critical factors in aquatic ERAs because many COECs accumulate to elevated concentrations in sediments, and therefore act as sources of chemicals to the interstitial (i.e., pore) water and overlying surface waters.

Aquatic receptors are, by definition, in continuous contact with the water. They are also in contact with sediments, either bed sediments covering the bottoms of the lakes, streams, and estuaries or suspended sediments that are in the water column. Aquatic receptors can be exposed to sediments through incidental ingestion while feeding or through contact of sediment with permeable membranes. The extent of exposure to chemicals in sediment varies with several factors, including bioavailability of COECs, sediment type, sediment and water movements, organism life stage and location in the water column, migratory movements, and feeding strategies.

Aquatic receptors can also be exposed to COECs by ingesting prey organisms that have bioaccumulated chemicals, typically organic compounds such as pesticides or PCBs. Evaluation of the potential for risk through exposure of aquatic receptors to COECs is increasingly complex for the three exposure media -- water, sediment, and prey. Because of this increasing level of complexity in assessing the potential for exposure and risk, water is the exposure medium often evaluated first, by screening against established water quality criteria and standards or laboratory bioassay results (see Chapter 5). Sediment contaminant concentrations can be compared to sediment standards, guidelines, or COEC sediment levels that are back-calculated from water criteria using chemical-specific K_p values in an equilibrium partitioning approach. Finally, potential risk from ingesting contaminated prey can be evaluated by using food ingestion models that consider all three pathways.

4.3.2.3 Exposure Route Modifying Factors for Aquatic Receptors

Numerous factors modify the extent of exposure to COECs in the aquatic environment. Although factors generally fit into physical, chemical, and biological categories, the factors act in combination with each other to affect the exposure of aquatic receptors to COECs, bioavailability of the COECs, and the toxicity of the COECs.

4.3.2.3.1 Physical Factors. Physical factors affect the release mechanisms that move COECs from the source

along a transport medium to the exposure point; physical factors also can influence the movements of receptors and their presence at the COEC exposure point. Referring to the aquatic ECSM in CS 3, these physical factors include discharge, leaching, infiltration, erosion, dilution, settling, and resuspension on the physical media.

An example can serve to illustrate the physical factors that influence the presence and concentration of COECs at the exposure point. COECs in contaminated soils can move into groundwater through leaching from contaminated soils. Groundwater then moves toward surface waters at a given rate that, when multiplied by a COEC concentration in groundwater, results in a loading rate to the surface water. Groundwater typically moves through the interstices of the sediment where the COECs can accumulate in the sediment or can be diluted when mixed with the surface water. Grain size and shape of the sediment particles affect the tendency of COECs to adsorb onto the sediment, thereby reducing their mobility in the aquatic environment. Throughout the pathway, chemical factors such as pH, oxidation-reduction potential (Eh), and presence of other chemicals interact with the physical factors described and affect the presence, concentration, and form of the COECs at the exposure points (sediment and surface water).

Physical factors can also influence the movement and location of aquatic receptors, thus affecting their exposure to COECs. In an interactive scenario analogous to that described above for physical and chemical factors, physical factors interact with biological factors that also affect exposure of the receptors. Physical factors such as current velocities, water temperature, and water salinity can influence seasonal migratory movements and rates of growth that, in turn, can influence the location of the receptors relative to COEC concentrations.

4.3.2.3.2 Chemical Factors. Chemical factors can affect the chemical and physical form of the COECs, their bioavailability, and ultimately, their toxicity to receptors. In fresh water, pH, Eh, hardness, and the presence of dissolved and particulate organics affect the form and availability of many metals. The overall effect of these confounding natural factors on toxicity of metals is reflected in the water effect ratio (WER), which is based on the relative toxicities of a COEC when tested in a dilution series using laboratory water versus the same COEC tested using upstream natural water as dilution water.

In sediments, some of the same chemical factors influencing exposure of receptors to COECs in water also affect exposure to COECs in sediments. Two other chemical factors, total organic carbon (TOC) and acid volatile sulfide (AVS), strongly affect exposure of receptors to COECs in sediments. Increased levels of organic carbon in sediments tend to bind nonpolar organics to the sediment. This effect is reflected in the chemical-specific organic carbon-water partition coefficient, K_{oc}.

AVS affects the binding of metals to sediments by providing additional binding locations for metals. The metals primarily affected include cadmium, copper, lead, nickel, and zinc. These metals replace iron in iron sulfide complexes. If the concentration of AVS exceeds the combined concentration of these five metals as determined through a simultaneous extraction procedure referred to as SEM (i.e., SEM/AVS ratio is greater than 1.0), the mobility of the metals is decreased due to the abundance of binding locations. If the AVS level is lower than the SEM level (i.e., SEM/AVS < 1.0) there may be a lack of binding locations, and the five SEM metals are more available (and potentially toxic) to receptors. The results of the AVS and SEM analyses should be interpreted on a weight-of-evidence basis because of the confounding influence of other chemical and physical factors.

4.3.2.3.3 Biological Factors. Several biological factors affect the co-occurrence and exposure of aquatic receptors to COECs in the water and sediment exposure media. Similar factors also affect the exposure of prey organisms to COECs that can bioaccumulate in the prey tissues, thus contributing to the overall exposure of receptors to bioaccumulative COECs.

Some of the more important biological factors affecting exposure to COECs are life stage, feeding strategy, and migratory movements of the receptors. In a typical exposure scenario, COECs are found in sediments and water but are at higher concentrations in the sediments. Several benthic invertebrate species (e.g., oysters) have larval stages that are planktonic and adult life stages that are sessile (i.e., attached to a substrate). If that substrate or the surrounding sediment has elevated COEC concentrations, the adult is likely to be exposed to COECs, whereas the larval stage is less likely to be exposed since it is not directly associated with the sediment.

Feeding strategy can also directly influence exposure to COECs. If a receptor feeds in or along the sediment and COECs are at elevated levels in the sediment, the receptor is apt to be exposed to COECs through ingestion of prey organisms that have accumulated COECs and incidental ingestion of sediment. If a receptor feeds higher in the water column, it is less likely to be exposed to COECs in

sediments and sediment-related prey. If a receptor is an upper-level predator (e.g., black drum), it is apt to be exposed to bioaccumulative COECs through ingestion of primary or secondary consumers that have elevated levels of COECs in their tissues. In contrast, a primary consumer that eats plant material is less apt to be exposed to COECs since chemicals are not apt to be accumulated to elevated levels in the vegetation.

Migratory movements of receptors can directly affect exposure to COECs. The effect of migratory movements is readily illustrated through a comparison of a fish that follows anadromous migratory patterns (i.e.. moves from the ocean through an estuary into fresh water to spawn and then returns to the ocean) to a resident species of the estuary. If the estuary and its sediments have elevated levels of COECs, the resident species is exposed throughout its life, while the anadromous species is only briefly exposed. In the case of the migratory species, although its year-round exposure cannot be confirmed, it often is assumed that the species is exposed to the COECs only while it is in the vicinity of the contaminated sediment or other exposure medium.

The manner in which several of these biological factors may affect the exposure characteristics of receptors to COECs provides an emphasis for going beyond mere listing of species present which are formulated during the initial site description and/or reconnaissance. A functional evaluation of how the species present actually use the habitat is necessary. Uses such as spawning grounds, nursery grounds, or adult food foraging should be distinguished so that significant biological factors influencing exposure may be integrated in any evaluation of exposure routes.

4.3.2.4 Exposure Routes for Terrestrial Receptors

Typical exposure pathways and routes for terrestrial (and wetland) receptors are illustrated in CS 3. Similar to the aquatic ECSM, the terrestrial ECSM enables the risk assessor to visualize where and how COECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The three principal potential exposure routes for terrestrial (animal) receptors are: dermal absorption, inhalation, and ingestion. Exposure route for plants include both root uptake and foliar absorption.

4.3.2.4.1 Dermal Contact with Soil, Sediment, Water, and Air. Dermal contact with soil, sediment, or water is a potentially significant exposure route for soil-dependent terrestrial animals (e.g., invertebrates and microbes) or animals which spend considerable time submerged in surface water (e.g., muskrat, beaver). Wildlife may receive indirect dermal exposure by brushing against surfacecontaminated vegetation. However, dermal absorption is generally an insignificant intake route for terrestrial wildlife, as such receptors are largely protected by their fur, feathers, or scales. Soils that are covered by pavement are unlikely or impossible to contact. and the assessment should account for this accordingly. Further discussion of the dermal exposure route is presented in Section 4.4.5.3.

4.3.2.4.2 Inhalation Exposure to Air. Inhalation exposure by terrestrial receptors could occur to both vapor phase chemicals and particle phase chemicals. Quantitative methodologies for evaluating this exposure route in terrestrial fauna are not well-established, but have been developed in order to evaluate wildlife exposure to herbicide sprays (USDOI 1991). Consideration should be given to the chemical form applied, degree of chemical absorption, methods for estimating exposure point concentrations, and toxicity values where there is the potential for this to be a significant pathway. Further discussion of the inhalation exposure route is presented in Section 4.4.5.2.

4.3.2.4.3 Ingestion of Water. Ingestion of water by terrestrial wildlife should be examined where there is a significant water source. Analysis of unfiltered surface water samples best represents chemical concentrations to which a terrestrial receptor may be exposed. Potential exposure of biota to chemicals in small, temporal, surface water puddles is typically not evaluated (unless concentrations are extremely toxic) as the exposure is likely to be insignificant compared to exposure from other pathways.

4.3.2.4.4 Ingestion of Soil or Sediments. Ingestion of soil or sediment should be considered for all exposure scenarios that provide direct access to soil. Many wildlife species ingest soil while feeding, but ingestion rates are known for only a few species. Soil ingestion rates have been measured for certain livestock in order to estimate pathways for human exposure (EPA 1990d). Similar estimates of soil ingestion rates for grazing wildlife may also be used.

Except for earthworms and some other soil invertebrates, most terrestrial animals do not "eat" dirt, but ingest only a limited amount of soil incidental to feeding (typically less than 10 percent of food intake). Deliberate ingestion of soil may occur under some circumstances, such as for

sodium (salt licks) or calcium content, or for grit. Soil intake may also be a result of incidental (direct) ingestion from soil adhered to the surface of food/prey items or from grazing, preening/cleaning, or burrowing activities. Under certain site conditions, the soil in the gut of earthworms may be an important exposure medium for animals that eat these organisms (Beyer et al. 1993). The sandpiper group is generally thought to have the highest rate of soil/sediment ingestion (7 to 30 percent) due to their diet of mud-dwelling organisms. Relatively high rates are also reported for wood ducks (11 percent), raccoon (9.4 percent), and woodcock (10.4 percent), which feeds extensively on earthworms, and Canada goose (8.2 percent) (Beyer, Connor, and Gerould 1994). Soil ingestion rates for small rodents are reported at less than 2 percent (Beyer, Connor, and Gerould 1994).

4.3.2.4.5 Ingestion from Diet. Exposure of high trophic level receptors to lower trophic level plant or animal species into which chemicals have accumulated should be considered in cases where COECs have the potential to biomagnify. Organic chemicals with high log KOW (>3.0, EPA 1994f) or high molecular weights (i.e., pesticides and PCBs) are more likely to be transferred through the food web than those with low molecular weights. Plants can take up chemicals with low log $K_{,,}$ values by way of their roots, but cannot transport significant amounts of chemicals with high molecular weights and high low K_{ow} values in the same manner (EPA 1989c). Such chemicals can, however, be transported via the air pathway and deposited and adsorbed to plant surfaces (leaves, etc.). Predator species at the top of the food web are the most vulnerable to chemicals that biomagnify. In general, long-lived and larger species (that accumulate fat) have a greater opportunity to accumulate these compounds as well. Also, higher trophic level species, particularly bird species, may be more sensitive to the COECs than the animals on which the birds prey. For terrestrial species, BCFs as little as 0.03 can be significant if the residue is toxic (EPA 1989a).

4.3.2.4.6 Plant Uptake. The soil-plant system is an open system subject to inputs, contaminants and fertilizers, and to losses, through plant consumption, leaching, erosion, and volatilization (Alloway 1990). Factors affecting the contaminant amounts absorbed by a plant are those controlling: (1) concentration and speciation of the contaminant in the soil solution, (2) movement of the contaminant from the bulk soil to the root surface, (3) transport of the contaminant from the root surface into the root, and (4) translocation from the root to the shoot (Alloway 1990). Plant uptake is dependent on both the total quantity of the contaminant in soil as well as the root mass present. Terrestrial plant uptake of contaminated water can be a potentially significant pathway if the plant is a wetland species or a phreatophyte (plants that depend on groundwater for their moisture). The uptake route for water is generally insignificant for xerophytic and mesophytic plants which have more shallow root systems and depend on surface water from rainfall.

In addition to the root absorption, plants can absorb contaminants through their foliage. Foliar absorption of contaminants (in the form of solutes) depends on the plant species, its nutritional status, the thickness of its cuticle, the age of the leaf, the presence of stomata guard cells, the humidity at the leaf surface, and the nature of the solutes (Alloway 1990). The uptake route from air to terrestrial plants can be a potentially significant pathway for vapor phase and particulate phase COECs. While chemical concentrations found in the air pathway generally pose only a minimal risk to animal species, lichens, in particular, and trees can be especially sensitive to airborne contamination. In ERAs conducted near forested areas, air may be an important environmental transport medium for certain plant groups.

4.3.2.5 Exposure Route Modifying Factors for Terrestrial Receptors

Numerous factors influence the spatial distribution and abundance of a population of animals relative to the spatial extent of contamination. Exposure modifying factors such as home range, mobility, and life-cycle attributes (breeding seasons, longevity) should be evaluated in the exposure characterization. Normalizing factors (e.g., body weight, growth rate) for the various receptors am also to be considered during exposure quantitation.

4.3.2.5.1 Area Use. Home ranges and feeding territories should be considered as they may greatly influence potential exposure. The size and spatial attributes of a home range often are determined by foraging activities, but also might depend on the location of specific resources such as dens or nest sites. Home ranges depend on habitat quality (e.g., carrying capacity), with home range sizes generally increasing as habitat quality decreases to a condition beyond which the habitat does not sustain even sparse populations. Home ranges can also vary by sex, season, and life stage. Population density (the number of organisms per unit area) also influences potential exposure.

The mobility of a receptor is usually expressed in terms of the average foraging range of the key receptor (or similar species) under consideration. Mobile receptors

typically include the larger vertebrates and grazing species (deer, elk, antelope), predators (fox, coyote), migratory birds (robin), and predatory birds (hawk, eagle, falcon). The foraging areas of these transitory species are likely to be several square miles. Smaller mammals and birds constitute a category of mobile receptors whose foraging areas range from a fraction of an acre to several acres. Plants, soil organisms, and most flightless invertebrates can be considered to be stationary due to the small area within which they live their lives. In each case, to quantify chemical intake for the key receptor, an area use factor should be applied to account for the foraging range of the key receptor, as compared to the areal extent of the contaminated area. The area use factor is defined as the ratio of home range, or feeding/foraging range, to the area of contamination or the site area under investigation.

4.3.2.5.2 Exposure Frequency. Exposure frequency is another type of modifying factor that can be used to adjust exposure and chemical intake for a key receptor. Resident species, rather than migratory species, should be evaluated first (when they are present), due to the longer exposure duration potential of the resident species. Migratory species should be evaluated where there is the potential for acute toxic effects from infrequent exposure or where exposure pathways present a greater exposure potential. Magnitude and frequency of exposure should be taken into consideration where the assessment endpoint and toxic effect are based on chronic exposure duration in the test organism.

4.3.2.5.3 Seasonal Activity Patterns. Many seasonal or life-cycle attributes affect an animal's activity and foraging patterns in time and space and their exposure potential. For example, many species of mammals, reptiles, and amphibians hibernate or spend a dormant period in a burrow or den during the winter months. Longevity and mortality rates also influence exposure potential and are important in determining potential for chronic exposures.

Seasonal variability may also affect the interpretation of ecological data and should be considered in the design of any sampling plan. Data obtained during any short period could be accurate, but only for that period. For example, pinyon mice apparently suffer substantial winter mortality (Morrison 1988). Trapping only in fall or spring would falsely indicate a relatively high or low population size, respectively. A full year of sampling is generally required to adequately characterize an ecological population. Some vertebrate population cycles, however, can take much longer: e.g., a 23-fold difference between peaks and low numbers in snowshoe hares was described in one 15year study (Keith 1983). and it took 12 years for a relationship between conifer seed crop and red squirrel abundance to be repeated (Halvorson 1984).

4.3.2.5.4 Dietary Composition. Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is an important consideration for higher trophic level organisms indirectly exposed to chemicals that bioaccumulate or biomagnify.

4.3.2.5.5 Habitat Preferences. Many wildlife species have habitat preferences that may increase or decrease their potential exposure to contaminants. Woodcocks, for example, will remain longer feeding in fields with tall cover than in those with short vegetation (Hull and Suter 1993). Robins, on the other hand, prefer fields or lawns maintained by regular mowing.

4.3.2.5.6 Foraging Style. Animals with different foraging styles may also have different morphologies and activity patterns that ultimately influence exposure to contaminants. Piscivorous avian species, for example, can be classified into three general types of foraging styles: raptorial predators (bald eagle), diving and swimming predators (common merganser), and wading predators (great-blue heron).

4.3.3 Exposure Profiles

Using information obtained from the exposure analysis, the exposure profile quantifies the magnitude and spatial and temporal patterns of exposure. The exposure profiles developed for the ecological receptors and COECs serve as input to the risk characterization.

4.3.3.1 Quantitation of Exposure

For soil-dependent organisms (plants, soil invertebrates, soil microbes), soil exposure concentrations are directly evaluated against soil criteria, similar to AWQC for aquatic organisms. Standard soil criteria like the AWQC are not currently available, but are under development by EPA. ORNL (1994) has recently published toxicological benchmarks for terrestrial plants and soil/litter invertebrates.

For wildlife, chemical intakes am estimated for exposures occurring from complete exposure pathways for each receptor group. The exposures are quantified with respect to the magnitude, frequency, and duration of exposure to derive an estimate of chemical intake.

Chemical intake by wildlife is estimated by combining two general components: the chemical concentration

component and the intake/exposure factors component. In the following subsections the estimation of the exposure point concentrations, discussion of the selection of intake and exposure factors, and the specific methods of combining them mathematically are presented.

4.3.3.2 Determining Exposure Concentrations (Aquatic and Terrestrial Scenarios

Exposure concentrations represent the chemical concentrations in environmental media that the receptor will contact. Exposure concentrations may be derived from either data obtained from sampling or from a combination of sample data and fate and transport modeling, both of which are described below.

For current (and perhaps some future) exposure scenarios where current site data are anticipated to be reasonably reflective of exposure concentrations over the exposure period, the exposure point concentration can be directly derived from site data. For future (and perhaps some current) exposure scenarios, where current site conditions are not anticipated to be reasonably reflective of exposure concentrations over the exposure period, some form of fate and transport modeling or degradation calculations can be applied. However, these too will be based upon current site conditions as a starting point. The available data need to be examined critically to select the most appropriate data in each medium to describe potential exposure. These data sets can vary depending on the receptor-specific exposure factors. For example, soil data for soil-dependent organisms (earthworms) and burrowing mammals would include samples from greater depths than direct soil exposure for large herbivores. General factors to consider when deriving exposure concentrations are identified in Exhibit 13.

Since the exposure point concentration used in the assessment is a value that represents the most likely concentration to which receptors may be exposed, a value that reflects the central tendency of the data is appropriate to use. In order to account for uncertainties in the ability of the measured data to reflect actual site conditions, the concentration relating to the 95% UCL of the arithmetic mean is usually used as the exposure point concentration. In cases where the 95% UCL concentration exceeds the maximum detected value (which can occur in small data sets or data sets with a large variance), the maximum value is used[9] (see CS 11). It is worth noting that use of the central tendency value may not adequately address chemicals that are highly bioaccumulative or biomagnify.

EPA has recommended that the approach presented in Gilbert (1987) be used to calculate the exposure point concentration term (EPA 1992h). This approach derives the 95% UCL of the arithmetic mean, using log-transformed data. EPA recommends assuming a log-normal distribution unless an alternate distribution can be demonstrated to be appropriate. If a normal distribution is appropriate for the data the Student's t test can be applied. Exhibit 14 presents methods to calculate the 95% UCL concentration by these two distributions.

Often in data sets, a number of data points for a given chemical in a given medium will be reported as undetected or less than some quantitation limit.[10] Common errors in reporting and handling these data can occur and include: (1) omission of detection limits, (2) failure to define detection limits which am reported, and (3) unjustified treatment of nondetects as zero. In calculating the sample mean (x) and sample standard deviation(s), some method of handling these "less than" values is needed. Also, the uncertainties in statistical comparisons and variance biasing that can ensue when nondetection samples are assumed to be a single value should be addressed.

Four options for the treatment of nondetect values are discussed in Gilbert (1987):

---

[9] Reasons for the 95% UCL value exceeding the maximum values are numerous. Such a circumstance may be indicative of incomplete site characterization. This circumstance may also reflect high variance due to biased, purposive sampling rather than random sampling.

[10] Analytical laboratories frequently code samples as "below detection" when the actual concentration was detectable with the method employed but fell below the Contract Laboratory Program (CLP) contract reporting limit. This situation is easy to spot because all "below detection" samples will have the same value. Sample specific (not generic) practical quantitation limits (PQLs) or method detection limits (MDLs) should also be reported.

CASE STUDY 11

CALCULATION OF EXPOSURE POINT CONCENTRATIONS (TERRESTRIAL ECOSYSTEM)

The exposure area for a small mammal is defined as the area of the former metal scrap piles. Therefore, data from locations SS-1 through SS-4 describe the exposure area and are combined to derive the exposure point concentrations. Assuming a log-normal distribution and applying the statistical approach for calculating the 95% UCL on the arithmetic mean for a log-normally distributed population (as recommended by EPA), the following exposure point concentrations are derived:

Chemical	Mean Conc	95% UCL	Max Conc
Cadmium (mg/kg)	85.6	104.3	100

Note that the 95% UCL concentration is greater than the maximum detected concentration. This occurred because the small sample size resulted in a high "H" statistic value and an artificially high 95% UCL. Since the 95% UCL exceeds the maximum detected value, the maximum value is used as the exposure point concentration. This concentration will be used as the exposure point concentrations for soil ingestion by wildlife and soil contact by soil-dependent organisms.

- Use only the quantified values
- Assume the nondetected values are equal to the quantitation limit.
- Assume the nondetected values are equal to zero.
- Assume the nondetected values are some value between zero and the quantitation limit, such as one-half of the quantitation limit.

The first three methods are biased for both the population mean (μ) and the population variance (σ^2); the fourth is unbiased for p if all measurements between zero and the quantitation limit have a uniform distribution. EPA discusses use of these approaches and recommends using one-half of the sample quantitation limit (SQL) if there is reason to believe that the chemical is present in the sample (such as being detected in other similar samples), or using the full SQL if there is reason to believe that concentrations are closer to the SQL than one-half of the SQL (EPA 1989f). The assumption of a value of zero for nondetects should be made only if site-specific information indicates that a chemical is not likely to be present in a sample. In *RAGS I*, EPA (1989f) indicates that omission of nondetected results is not appropriate. Additional discussion can be found in EPA Region III's (1991f) *Technical Guidance on Chemical Concentration Data Near the Detection Limit.*

In certain situations, an unusually high quantitation limit may be assigned to a nondetected result due to matrix interferences, high concentrations of other chemicals in the sample, presence of blank contamination, or other factors. When one-half (or all) of this quantitation limit is used to derive summary statistics, the mean concentration may exceed the maximum detected value. When the 95% UCL concentration is calculated, it, too, will be above the maximum detected value. In these situations, guidance recommends using the maximum detected value in place of the 95% UCL concentration. It should be noted, however, that if many of the undetected results have unusually high detection limits, these high limits may be masking the presence of the chemical. In this case, the utility of the data set and the need for additional analysis should be examined.

As an option, to obtain a more representative mean and UCL concentration, the sample with the unusually high quantitation limit can be removed from the calculation of the mean concentration, reducing the sample number ("n") by one. If the resultant mean concentration still exceeds the maximum detected value, the next highest quantitation limit should be removed, and the mean recalculated. This process can continue until a mean concentration less than the maximum concentration is attained. The 95% UCL concentration then can be recalculated, as well.

Sample size influences the magnitude of the statistical confidence of the mean, as demonstrated by high 95% UCL concentrations for small sample sets. The reliability coefficients (the "H" or "t" value used in calculating the UCL concentration, obtained from statistical tables) are a function of the number of samples, and increase with a decreasing number of samples. The overall effect, then, of a small sample size upon statistical confidence is to increase the UCL concentration. In data sets in which minimum requirements have been set prior to sampling, the risk assessor should ensure that an adequate number of samples have been collected to minimize this problem.

Exposure point concentrations are also sometimes derived from a combination of measured data and the application of environmental fate and transport modeling. For the most part, measured data points are preferred over modeled data: where data are modeled, some level of validation and ground-truthing is required (exceptions include ERAs for proposed incinerator emissions/deposition). Common instances in which modeling may be used to predict exposure point concentrations include:

- When the potential exposure point is at a location other than those for which monitoring data are available (e.g., in offsite areas or locations in-between those which have been described).
- When the potential exposure is anticipated to occur in the future (e.g., proposed incinerator emissions).
- When the chemical concentrations are anticipated to change with time.
- When the potential exposure is in a medium other than those sampled (e.g., exposure to air impacted by contaminated soil, when only soil was analyzed).
- When the potential exposure point concentration is anticipated to increase with time (as with bioaccumulation into animal or plant species).
- When the bioavailable portion of the chemical concentrations is anticipated to change with time (e.g., seasonal AVS fluctuations, fluctuations

between fresh and saline water either with migration downstream or tidal influence).

Many fate and transport models are available with which to predict exposure point concentrations from existing site data. These models are presented in other references, including the following:

- *Superfund Exposure Assessment Manual* (EPA/ 540/1-88/001,4/88) (EPA 1988h).
- *AirlSuperfund National Technical Guidance Study Series* (Volumes I - V) (EPA 1989h,i; 1992i, 1993d: 1995g).
- *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants* (EPA-450/4-88-009, 9/88) (EPA 1988i).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-water Models* (EPA/600/8-88/075, 5/88) (EPA 1988j).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (EPA/600/8-87/042, 7/87) (EPA 1987a).
- *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites* (EPA/600/8-85/002, 2/85) (EPA 1985).
- *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions* (EPA/600/6-90/003, 1/90) (EPA 1990d).
- *Assessment and Control of Bioconcentratable Contaminants in Surface Water* (EPA 1991e).

The type of model and level of effort to be expended in estimating exposure point concentrations with models should be commensurate with the type, amount, and quality of data available. In general, it is best to begin with a model that employs simplified assumptions (i.e., a "screening level" approach) and determine whether unacceptable ecological risks are posed by the exposure point concentration estimated by this approach. If so, a more complex model that applies less conservative assumptions can be used.

The validity of the estimation provided by the model will strongly depend on the variables that are input to the models. Efforts should be taken to ensure the use of input variables that best reflect site conditions and that are not overly conservative.

Initial abiotic sampling designs are often not established with sampling for the selected key ecological receptors in mind. Often, biased sampling designs are selected in order to best characterize potential hot-spot conditions and the nature and extent of contamination. Calculation of a 95% UCL or averaging of these point concentration results tends to result in an overestimation of the exposure concentration (and risk) for larger mobile animals (deer, antelope) that don't forage onsite or at any particular spot for extended periods of time. Where the receptor's home range is greater than the contaminated area, area use and exposure frequency factors can be used to modify the areawide intake concentration. Where the receptor's home range lies within the contaminated area, alternate methods of removing the bias from the areawide exposure concentration (e.g., weighted average, Theissen polygons) data set can be used, but may result in an over- or underestimate of exposure. Probability analysis techniques (Monte Carlo) and programs (e.g., Crystal Ball@) are also gaining greater acceptance as a means to provide a more realistic estimate of actual exposure conditions by generating a distribution of probable exposure concentrations (See Appendix E).

4.3.3.3 Calculating Intake for Terrestrial Wildlife

The following discussion of terrestrial wildlife intake focuses on the oral ingestion route only. Oral intake (ingestion) of three environmental media (food, water, soils/sediment) are the principal routes evaluated in a Tier I terrestrial ERA, as they typically represent the most significant exposure pathways. Quantitative data and methodologies by which to calculate inhalation and dermal contact rates for various terrestrial wildlife (or livestock) are generally lacking: limited guidance on these intake routes are provided by EPA (1990d, 1993e) and USDOI (1991).

For each receptor, the following four exposure factors are considered in the calculation:

- Food Intake (FI) - These rates can vary by age, size, and sex and by seasonal changes in ambient temperature, activity levels, reproductive activities, and the type of diet consumed. Food ingestion rates are available in the published literature for a limited number of wildlife species. Methods for estimating food ingestion rates are provided in EPA's (1993e) *Wildlife*

Exposure Factors Handbook (see Exhibit 15). Food ingestion rates are typically expressed on a wet-weight basis. Where results from wildlife laboratory studies are expressed on a dry weight basis, this difference may be ignored as the moisture content of most laboratory studies is typically less than 10 percent water (Beyer and Stafford 1993).

- Dietary Composition (DC) - Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is typically expressed as percentage of total intake on a wet-weight basis.

- Water Intake (WI) - Water consumption rates depend on body weight, physiological adaptations, diet, temperature, and activity levels. Some species (e.g., deer mouse) can meet most of their daily water requirement with only the water contained in their diet. Water ingestion rates can be estimated using allometric equations published by EPA (1993e; see Exhibit 15).

- Soil/Sediment Intake - Soil or sediment intake is usually expressed as a percent of dietary intake. Data quantifying soil/sediment intake are limited; values for selected wildlife species are presented in the *Wildlife Exposure Factors Handbook* (EPA 1993e). As noted earlier, soil/sediment intake rates of up to 30 percent of diet are reported for some wildlife.

4.3.3.3.1 Intake Equations. Estimating contaminant exposure for wildlife consists of summing the exposure received from each separate source. Total exposure intake for terrestrial wildlife is represented by the following generalized equation (ORNL 1994):

$$E_{total} = E_{food} + E_{water} + E_{soil}$$

where

E_{total} = exposure from all sources

E_{food} = exposure from food consumption

E_{water} = exposure from water consumption

E_{soil} = exposure through consumption of soil and sediment (incidental or deliberate)

Exposure or chemical intake by terrestrial wildlife is reported as "average daily dose" on a body weight basis, i.e., milligrams chemical per kilogram body weight per day (mg/kg-bw/d). It is fundamental that exposure, chemical intake, and toxicity benchmark determinations be adjusted to account for body weight and dietary intake of the organism, to account for the differences in food intake relative to body weight of the various organisms being compared. Exposure evaluations (and toxicity benchmark selection) based on a comparison of dietary chemical concentrations (i.e., milligrams chemical per kilogram food, mg/kg) amongst wildlife receptors (e.g., deer and rabbits) are sometimes mistakenly attempted in an ERA as a means to "simplify" the quantitation process. The following equations for chemical intake exemplify the simplified assumption models commonly used in a baseline ERA. More complex assumption models can be found in the *Wildlife Exposure Factors Handbook* (EPA 1993e).

Chemical intake is estimated by applying the following generic equation to each exposure source (e.g., food):

$$\text{Daily Intake}_{food}\ (\text{mg-chem/kg-bw/d}) = \frac{C \times FI \times EMF}{BW}$$

where

C = concentration of chemical in food (i.e., mg-chem/kg-food)

FI = food intake rate (kg-food/day)

EMF = exposure modifying factors such as area use (percent of home range that is contaminated) or exposure frequency (percent of time spent in contaminated area) that describe the magnitude and frequency of exposure (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

Selection of appropriate intake and exposure modifying factors is a critical component of the assessment, for these values largely determine the overall risk estimates. The *Wildlife Exposure Factors Handbook* (EPA 1993e) presents exposure profiles for selected species of birds, mammals, and reptiles and amphibians. Each species profile provides a series of tables presenting values for normalizing (body weight) and contact (intake) rate

factors, exposure modifying factors (home range), dietary composition, population dynamics, and seasonal activity patterns. Additional information on wildlife exposure factors can be found in the published literature including ORNL's (1994) *Toxicological Benchmarks for Wildlife.* Allometric equations for estimating wildlife feeding and drinking rates are provided in Exhibit 15. Some general points that should be considered when selecting exposure factors are identified in Exhibit 16. In an ERA, all exposure and intake factors applied to the assessment should be identified in tabular form, with the source of the value identified and a rationale for the use of the value presented.

If C and FI vary over time, they may be averaged over the exposure duration (ED). However, it is not always appropriate to average intake over the entire exposure duration: For example, a given quantity of a chemical might acutely poison an animal if ingested in a single event, but if that amount is averaged over a longer period, effects might not be expected at all. Similarly, developmental effects occur only during specific period of gestation or development. C, FI, and BW should be selected so as to be comparable to the specific reference toxicity value that is used.

Wildlife can be exposed to contaminants in one or more components of their diet and different components can be contaminated at different levels. For example, the diet of the deer mouse, an omnivorous key receptor commonly assessed in ERAs, primarily consists of invertebrates and terrestrial plants. The daily intake for the deer mouse is thus expressed as [(chemical concentration in invertebrates x % ingested) + (chemical concentrations in terrestrial plants x % ingested) x daily food intake] / deer mouse body weight. To calculate daily dose for diets with more than one component, the following generic equation may be used:

Daily intake (mg-chem/kg-bw/d) =

$$\frac{[(C_1 \times FI_1)\, f_1 + (C_2 \times FI_2)\, f_2 + \ldots (C_i \times FI_i)\, f_i] \times EMF}{BW}$$

where

C_i = concentration of chemical in food (i.e., mg-chem/kg-food or ppm)

FI_i = food intake rate (kg-food/day)

f_i = fraction of food item in diet

EMF = exposure modification factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

The same generic equation can be used to estimate daily intake of the contaminant from food, water, and soil/sediment ingestion routes. For example, to calculate the daily dose for a receptor exposed to a contaminant in diet and water, the following equation may be used:

Daily intake (mg/kg-bw/d) =

$$\frac{[(C \times FI) + (C \times WI)] \times EMF}{BW}$$

where

C = chemical concentration in food or water (i.e., mg/kg, mg/L, ppm)

FI = food intake rate (kg-food/day)

WI = water intake rate (L-water/day)

EMF = exposure modifying factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

In order to describe a range of potential exposures presented by a site, the ERA may assess more than one potential exposure scenario. Use of a single expression of potential ecological risk does not provide information on the possible range of ecological risks, and may not allow the risk manager to evaluate the "reasonableness" of the single estimate. Current risk assessment guidance for human health suggests the strategy for determining the exposure point concentration for soils should depend on spatial contaminant distribution. If a contaminant is widely distributed throughout the site, the exposure point concentration should be based on the 95% UCL of the arithmetic average for all site samples, including non-detects. However, if the contamination is unevenly distributed, i.e., "hot-spot" areas exist, these areas should be evaluated by determining exposure concentrations in these areas. A percentage of time that the receptor spends on the site in these "hot-spot" areas should be factored into the intake equation. Use of a "hot-spot" high end as well as use of the 95th UCL exposure scenario are also applicable to ecological risk. Presentation of these and other scenarios (e.g. central tendency) provide information

about the range of potential risks to the ecological receptors.

4.3.3.3.2 Intake Variable-s. To develop a "high end" assessment, EPA recommends identifying the most sensitive parameters and using maximum or near maximum values for one or a few of these variables, leaving other variables at their mean values. Adopting maximum values for all intake and exposure parameters will virtually always result in a risk estimate that is above that experienced by the most exposed receptor and is, therefore, inappropriate. EPA human health guidance *(RAGS I)* recommends applying 90th or 95th percentile values for the exposure point concentration term" and exposure frequency variables, and average values for other parameters such as body weight.

The average exposure (central tendency) is derived by applying average values for all intake and exposure (e.g., area use) parameters. Although description of an average exposure is not particularly useful when exposure varies greatly across all potentially exposed populations, it can provide information on the extent of impact of the exposure parameters that were maximized in the high end exposure. Use of a median value for exposure parameters, such as a geometric mean rather than an arithmetic mean, is more meaningful since it represents a midpoint value (i.e., half the population above and half below). Specific ERA guidance is lacking regarding the use of average versus 95th UCL values for exposure frequency and intake variables, as quite often are the data to calculate such values for specific ecological receptors.

Contaminants may enter terrestrial food chains directly from soil/sediment, water, or air or indirectly through the consumption of plants (producers) or animal prey (consumers). The following sections discuss means for determining chemical concentrations in plants and prey.

4.3.3.3.3 Estimating Chemical Concentrations in Plants. The three principal mechanisms by which contaminants can bioaccumulate in plants include: uptake by roots, direct deposition on exposed plant tissues, and air-to-plant transfer of vapor-phase contaminants. The dative importance of each pathway to the wildlife consumer depends on the specific plant, the contaminant, site-specific physicochemical conditions, and the preference of the wildlife receptor for the particular plant.

The plant-soil bioaccumulation factor (BAF_{plant}) or transfer coefficient is a measure of a contaminant's ability to accumulate in plant tissue and is defined as the chemical concentration in the plant (dry weight) divided by the chemical concentration in soil (dry weight). Bioaccumulation factors may be derived differently for inorganic and organic chemicals, but they are generally dependent on the bioavailability of the chemical in the soil or soil solution. Information and data on chemical transfer from soils, particularly sludge-amended soils, to a variety of crop species are available in the published literature (EPA 1983, USDA 1983, DOE 1984).

A number of models are also available for determining plant uptake of contaminants from soil (Kabata-Pendias and Pendias 1984, Briggs, Bromilow, and Evans 1982, Topp et at. 1986). Root uptake of numerous contaminants, however, is inefficient and much of the contaminant concentrations found in plants results from volatilization and leaf uptake (Suter 1993). Some methods for calculating chemical concentrations in plant tissue due to root uptake and air to plant transfer are published by EPA (1990d). Other methods are available in the published literature. Quantitative structure activity relationship (QSAR) models for determining combined root and leaf uptake of organic chemicals in soils are presented by Topp et al. (1986) and Travis and Arms (1988).

4.3.3.3.4 Estimating Chemical Concentrations in Animal Prey. The animal prey that higher trophic level predators usually consume as food take up contaminants from the food chain by ingesting soil-dependent organisms (plants, soil invertebrates), lower trophic level consumers, or soil and water directly. Methods for determining BAFs or biotransfer factors to livestock tissue are available for a variety of chemicals in plants such as grain (corn, oats, wheat, etc.), forage (pasture grass, hay), and silage (EPA 1990d). Similar methods for wildlife tissue are generally not available and thus the livestock factors are sometimes used.

Models for determining the uptake and transfer of chemicals through various food chains are becoming more numerous in the literature (Winter and Streit 1992, Fordham and Reagan 1991). BAFs can oftentimes be estimated for a receptor of interest based on food chain data presented in the published literature or in studies

[11] According to EPA (1992h) guidance, the chemical concentration relating to the 95% UCL of the mean is applied as the exposure point concentration term for both the average and the reasonable maximum exposure (RME) scenarios. Although an upper bound value, this concentration is descriptive of the mean and accounts for the uncertainty associated with measurements of the "true" mean.

conducted at Superfund sites where tissue sampling was performed. Studies on the accumulation of elements by earthworms, as well as direct toxic threshold levels, are becoming more abundant due to the close association between soil contamination and earthworms and the wide variety of earthworm predators (Beyer 1990, Beyer and Stafford 1993). Several authors have published models for determining the uptake of organic chemicals by earthworms (Wheatly and Hardman 1968, van Gestel and Ma 1988, Connell 1989).

4.3.3.3.5 Bioavailability. The intake equations used in ERAs typically do not contain a factor to account for bioavailability or bioassimilation and therefore may predict an intake higher than one that would occur in actual circumstances. By not including a factor to consider bioavailability, it is assumed that 100% of the chemical detected in the medium is bioavailable (when combined with toxicity values, the risk associated with the absorption of the chemical in the animal study is derived). Modifications may sometimes be made to these intake equations to account for this factor, if the appropriate information is available.

Bioavailability refers to the ability of a chemical to be "available" in the body to interact and have an effect. There are many aspects to bioavailability; however, the type most of concern to ERAs is the ability of the chemical to be absorbed into the body. Although the medium on which the chemical is contained may be contacted, the chemical may not be absorbed for a number of reasons, including the chemical form, competition with other factors (e.g., food in the stomach), damage of the organ (e.g., stomach, lung), effect of the medium in which the chemical is contained, and others. While many of these cannot be reliably addressed in an ERA, chemical form and effect of the medium can be addressed.

The form of the chemical can affect the degree of absorption into a body. This factor is most important for chemicals that form compounds (such as metals and cyanide) and chemicals that can exist in different valence states (again, **some** metals). For example, soluble compounds of metals (e.g., barium sulfate) are readily absorbed through the stomach whereas insoluble forms (e.g., barium carbonate) are minimally absorbed. Usually, when environmental media are analyzed, chemicals are reported as an isolated entity (e.g., barium), and no information is provided on the form that existed in the medium. However, if the form of the chemical used at the site is known, and information on the absorption of that chemical form is available, the intake equation can be modified to account for a lesser absorption (see ORNL 1994). Defensible information should be available to make this modification.

The medium in which the chemical is contained also can affect the degree of bioavailability. This is most pronounced in media that demonstrate an ability to bind chemicals (such as soil and sediments). When ingested by wildlife, a competition occurs between retention of the chemical on the medium and absorption of the chemical into the body. Therefore, some of the chemical may be excreted from the body without having been absorbed and some may have been absorbed and available to exert an effect. Many factors can influence the degree to which the medium will bind the chemical, most of which cannot be reliably predicted (for example, nature of the medium [organic carbon or clay content, particle size], other chemicals being absorbed, pH, organ condition, etc.). In some instances, information may be available on the degree to which a particular medium affects specific absorption routes. If the information justifies modifying the intake equations, such a modification may be made.

In most assessments, it is generally assumed that environmental conditions are reasonably static and chemical concentrations remain constant over time, often for as long as 30 years. Such assumptions may be unreasonable. Chemical concentrations are usually reduced over time by degradation, migration, dilution, volatilization, or other removal processes. If these processes are known and can be quantified, a concentration that decreases over time can be derived for assessing intakes. If no allowances are made to decrease concentrations over time, risks will most likely be overestimated.

4.3.3.4 Exposure Characterization Summary

At the conclusion of the exposure characterization, the estimated chemical intakes for each exposed receptor group under each exposure pathway and scenario should be presented in tabular form. This presentation should include an identification of all pertinent factors (basis of exposure point concentration, use of models, if applicable, assumptions made regarding exposures, etc.). These intake estimates are combined with the COEC toxicity values, discussed in the following section, to derive estimates and characterize potential ecological risk.

Uncertainties associated with the estimation of chemical intake should be summarized at the conclusion of the exposure characterization. The basis for each uncertainty should be identified (e.g., use of a default parameter, propagation of error through multiple layers of exposure modeling), the degree of the uncertainty qualitatively

(low, medium, or high) or quantitatively estimated, and the impact of the uncertainty qualitatively (overestimate and/or underestimate) or quantitatively stated. Description and presentation of uncertainties are discussed further in Section 4.5.2.

4.4 Analysis Phase-Ecological Effects Characterization

The ecological effects characterization (toxicity assessment) includes a preliminary evaluation of chemical-specific ARARs, a summary of the types of adverse effects on biota associated with exposure to site-related chemicals, relationships between magnitude of exposures and adverse effects, and related uncertainties for chemical toxicity, particularly with respect to site biota. Ecological receptor health effects are characterized using EPA-derived critical toxicity values, when available, in addition to selected literature pertaining to site- and receptor-specific parameters.

The preliminary toxicity evaluation provides toxicological profiles centered on health effects information on site biota. The profiles cover the major health effects information available for each COEC. Data pertaining to site-specific species are emphasized, and information on domestic or laboratory animals is used when site-specific biota data are unavailable. Adequacy of the existing database is also to be evaluated as part of this task.

4.4.1 Objectives

The Tier I effects characterization fulfills two specific objectives in a risk assessment. First, available toxicological literature is reviewed to identify appropriate literature benchmark values to use. The toxicological literature forms the basis for developing summaries of the potential toxicity of the COECs for inclusion in the risk assessment. Second, appropriate reference toxicity values (RTVs) (EPA 1993e; also abbreviated TRVs by other authors) are developed using literature benchmark values and uncertainty factors to estimate potential ecological risks associated with key receptor chemical exposure. This is accomplished by reviewing the available information on COEC toxicity and summarizing the factors pertinent to the exposures being assessed. In the following sections, each of these components of the effects characterization is discussed.

The Tier I effects characterization is based on a desk-top hazard index (HI) or hazard quotient (HQ) approach. Numerous bioassessment tools,[12] however, are available to the risk assessor to employ for directly measuring or investigating toxicity, or even risk. While these bioassessment techniques are presented as a Tier II effort in this manual (see Chapter 5.0), it is advisable to consider these techniques early on in the planning process as a potentially expedient means to directly address the assessment endpoints, particularly in aquatic ecosystems. Bioassessment techniques offer several advantages over the HQ or model approaches to toxicity estimation: they

- Demonstrate whether the COECs are bioavailable.
- Evaluate cumulative impacts due to exposure to multiple COECs.
- Evaluate toxicity of COECs for which no RTVs can be found.
- Characterize the nature of the toxicity.
- Integrate media variations and spatially characterize toxicity.
- Monitor impacts before and after remediation.
- Develop remedial levels in terms of toxicity and then monitor effectiveness and success of remedial actions.

4.4.2 Sources of Literature Benchmark Values

The sources that should be consulted for literature benchmark values will vary with the type of organisms being used as ecological receptors (e.g., aquatic, terrestrial) and the level of effort (i.e., tier). If the level of effort (time and money) is limited as is the case in Tier I and possibly Tier II, then documents that summarize available ecotoxicological information will suffice. If a higher level of certainty in the data is an objective in the compilation of literature benchmark values, then the primary toxicological literature should be sought so that details of the toxicity test conditions can be reviewed, validity of the test results confirmed, and applicability to site conditions determined.

[12] An in-depth discussion of topics related to the use of bioassessment approaches in ERAs is available in the September 1994, Volume 2 series of *Eco Updates*.

Toxicologic information on chemicals in aquatic ecosystems is fairly plentiful, while that for terrestrial ecosystems is somewhat more limited. Most of the available toxicological information for soil-based exposures has been generated using soil-dependent biota. ORNL (1994) however, has recently published benchmark values for plants, sediment-associated biota, and terrestrial wildlife. Compilations of toxicological data for soil-dependent organisms (plants, invertebrates, and microbes) are available in the open literature (Hulzebros, Adema, and Dirven-Van Breeman 1993, Kabata-Pendias and Pendias 1984, USFWS 1990, Overcash and Pal 1979, Gough, Schacklette, and Case 1979, Callahan, Shirazi, and Neuhauser 1994). PHYTOTOX, a database dealing with the effects of organic and inorganic chemicals on plants, is also available for government, academic, and industrial users (Royce, Fletcher, and Risser 1984). A new EPA database, ECOTOX, which integrates aquatic and terrestrial receptor databases is expected to become available in late-1995 (see Appendix B, Information Sources).

Published ERAs, such as those reviewed in EPA (1993f) *Case Studies from a Risk Assessment Perspective,* offer additional sources of terrestrial and aquatic toxicity data. Toxicity data and information for developing wildlife RTVs also may be obtained from many of the same sources used for human health toxicity information, particularly where data on small mammals (rats and mice) are needed. Regional EPA and DoD (U.S. Army, U.S. Navy) BTAG/ETAG persons can also be contacted for assistance. Other sources for aquatic and terrestrial laboratory data are presented in Appendix B and include the following:

- EPA Criteria Documents. Include ambient water criteria documents, proposed sediment quality criteria documents, drinking water criteria documents, air quality criteria documents, and health effects assessment documents.

- USFWS Contaminant Hazard Reviews. (Author: R. Eisler, dates 19851994). This is a series of reports reviewing the hazards of over 25 metals and organic compounds to fish, wildlife, and invertebrates.

- Oak Ridge National Laboratory (ORNL 1994), Toxicological screening benchmarks for ERAs (available in PC-database). This series of reports includes benchmarks for terrestrial wildlife, terrestrial plants, sediment-associated biota, and aquatic biota, and soil and litter invertebrates and heterotrophic processes.

- Toxicological Profiles developed by the Agency for Toxic Substances and Disease Registry (ATSDR 1989).

- Aquatic and terrestrial toxicological data (and in some cases, literature citations). Available in public or on-line databases such as Toxline, BIOSIS, AQUIRE, ASTER, QSAR, HSDB, Ecological Abstracts, Biological Abstracts, Current Contents, Duckdata (USFWS).

- National Academy of Sciences publications such as *Mineral Tolerance of Domestic Animals* (1980).

- Integrated Risk Information System (IRIS). This is EPA's primary database for the reporting of up-to-date human health toxicity values that have been verified by the EPA. IRIS may be accessed through TOXNET and other commercial services. IRIS contains numerous chemical profiles that present verified chronic reference doses for laboratory animals. The study(s) from which the toxicity value was derived is summarized, and the method of derivation is explained (e.g., applied uncertainty and modifying factors, level of confidence, extrapolation model).

- Health Effects Assessment Summary Tables (HEAST). HEAST is published annually by EPA, and is a collection of interim and provisional toxicity values developed by EPA. Verified toxicity values are not presented in the most current version of HEAST: rather, the user is directed to IRIS. HEAST can be obtained through the National Technical Information Service (NTIS).

4.4.3 Selection of Literature Benchmark Values

Laboratory animals (rat and mouse) studies are generally classified by the U.S. Dept. of Health and Human Services (USDHHS) according to exposure duration: chronic (>365 days), intermediate or subchronic (15-364 days), and acute <14 days). In aquatic bioassay tests, test durations for acute toxicity tests are typically 48 hours for invertebrates and 6 hours for fish. Definitions of the terms chronic, subchronic, and acute, however, are often inconsistent, and depend on the organism being tested. Suter (1993) and EPA (1995b) arbitrarily consider chronic to be 10 percent of the organism's lifespan. According to EPA's health effects testing guidelines, chronic toxicity

tests should involve dosing over a period of at least 12 months. The organisms studied and study duration should be reported when compiling literature benchmark values.

In selecting data to be used in the derivation of the RTV, the nature of the observed endpoints is the primary selection criterion. Literature benchmark values which best reflect potential impacts to wildlife populations through resultant changes in mortality and/or fecundity rates should be used. Toxic responses such as elevated enzyme levels (e.g., elevated blood aminolevulinic acid dehydrase [ALAD] from exposure to lead) or increased tissue concentrations, while they may serve as good biomarkers indicative of an organisms's exposure, are not useful endpoints insofar as being relevant and indicative of adverse impacts to key receptor populations. Relevant intermediate and chronic endpoints are those which affect organismal growth or viability, or reproductive or developmental success, or any other endpoint which is, or is directly related to, parameters that influence population dynamics. The toxic effect manifested at the lowest exposure level is (generally) selected as the critical effect. For some ERAs, however, the lowest acute level also is selected for use in determining an acute RTV. Where the toxicity database is large enough, a dose-response curve may be generated and used as the basis to select a literature benchmark value or to determine the RTV.

The following factors should be considered when selecting literature benchmark values and developing RTVs for use in the risk assessment:

- Literature benchmark values should be obtained from bioassays having test conditions as similar as possible to onsite conditions. For example, water hardness, which affects the toxicity of many metals, should be the same in order to have the bioassay results applicable to site conditions.

- The literature benchmark values and RTV should correspond to the exposure route being assessed: in ERAs, this is most typically the oral exposure route (dermal exposure may be assessed using modified oral toxicity values).

- The RTV should be appropriate for the key receptor and toxicity endpoint being assessed: e.g., assessment of reproductive and developmental effects in mammals and birds would require at least two, but possibly four, RTVs. RTVs for different toxicity endpoints in different receptors or receptors groups may need to be developed.

- The literature benchmark value and RTV should correspond to the appropriate exposure duration period: subchronic (two weeks to one year) or chronic (greater than one year).

- The literature benchmark value and RTV should correspond to the chemical form being assessed (only applicable to some chemicals, but especially metals such as chromium [trivalent or hexavalent] and mercury).

The process for selecting benchmark toxicity values is flexible so that site-specific considerations can be incorporated. Careful consideration should be given to the development of benchmark toxicity values, as they may provide the preliminary information used to set the target cleanup levels at sites where remedial action is anticipated. In the Tier I HI or HQ approach, the RTV is essentially the measurement endpoint and the hazard ratios calculated are inherently no more protective than the nature of the toxic mechanism described by the RTV. Caution should be taken in the assessment and selection of the RTV. For example, if the RTV were based on "acute" lethality, it would not be protective of chronic exposure conditions.[13]

4.4.4 Development of Reference Toxicity Values

Determination of RTVs for terrestrial and aquatic organisms is dependent on both life style and life stage. Literature benchmark values and RTVs for organisms in aquatic ecosystems (e.g., benthic macroinvertebrates and fish) are generally concentration-based, but can be dose-based for amphibians and higher trophic level receptors (waterfowl and aquatic mammals). Amphibian exposure is perhaps the most difficult to quantify, as amphibians have both concentration-based aquatic life stages and dose-based terrestrial life stages. Terrestrial RTVs can also be either concentration-based (e.g., flora and soil invertebrates) or dose-based (e.g., vertebrate fauna).

---

[13] As Tier I assessment endpoints are typically phrased in terms of protecting populations, the RTVs focus on measures of growth, survival, and reproduction. Under some circumstances, it may be appropriate to protect lower levels of biological order and employ biomarkers as benchmark values. Additionally, certain biomarkers are indicative of conditions which have direct implications to assessment endpoints of growth, survival, or reproduction and are not merely exposure markers.

Federal AWQC are frequently used as the equivalent of an RTV for aquatic organisms. On some sites, AWQC may be judged to be overly cautious RTVs for the specific key receptors, if the organisms on which the AWQC are based are far more sensitive than any onsite receptors.

In these cases, toxicity information used to develop the original AWQC may be used in conjunction with **other** toxicity data and literature benchmark values to develop a more site- and receptor-specific RTV.

In terrestrial ecosystems, two types of RTVs are needed: concentration-based RTVs for soil-dependent organisms and dose-based RTVs for wildlife. RTVs for soil-dependent organisms (e.g., plants, earthworms) are similar to AWQC in that they are concentration based. RTVs for wildlife are similar to the critical toxicity values (reference doses) used in human health risk assessments. Unlike human health toxicity values, however, RTVs for terrestrial wildlife are generally not available and thus need to be developed by the risk assessor. In order to appropriately select and use RTVs and to identify assumptions and uncertainties associated with RTVs, an understanding of the general practice currently followed in selecting RTVs is needed. Site-specific RTVs for aquatic and terrestrial ERAs should be developed in consultation with local wildlife and regulatory agencies.

4.4.4.1 Development of Aquatic RTVs

As stated above, aquatic RTVs can be based on state or Federal AWQC. However, especially in the case of metals, toxicity can be significantly affected by site-specific factors. Factors that can affect site-specific values include: ambient water chemistry, different patterns of toxicity for different metals, metals fate and transport, and use of standardized protocol for clean and ultraclean metals analysis. Also, applicability of the chronic criterion or acute criterion to the species of concern should be confirmed. Because AWQC have been calculated to protect populations of the most sensitive aquatic species, these criteria may be over (or under) protective of the aquatic ecological receptor(s) selected for the risk assessment. Methods used to calculate AWQC are described in Appendix A of the "Gold Book" (EPA 1986b) and more recently in the EPA's *Water Quality Standards Handbook* (EPA 1993g) and *Interim Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* (EPA 1992j, 1993c, 1995f). To determine the basis for a particular chemical, the AWQC document for that metal or compound should be consulted. As is the case with literature benchmark values, use of AWQC for RTVs may involve division of the criterion by uncertainty factors to account for greater sensitivity or uncertainty regarding the selected site receptor as compared to the AWQC species tested, life stage, test endpoint, and test duration. In the case of metals, the basis (total, total recoverable, or dissolved concentration) for the RTV or criterion and the chemical concentrations to which it is compared should be verified and consistent.

4.4.4.2 Development of Terrestrial RTVs for Soil-Dependent Organisms

EPA is currently evaluating the development of standardized protocol for deriving ecological effects-based soil criteria for contaminated sites. EPA plans to use an approach similar to that used for calculating sediment quality guidelines for the National Status and Trends Program (NSTP) (Long and Morgan 1990). This method uses a percentile of the effects data set or combined effects and no effects data set to estimate a concentration in the sediment expected to cause no adverse biological effects.

ORNL (1994) has published two documents containing benchmarks useful for screening potential COEC effects on terrestrial plants and litter invertebrates/heterotrophic processes (e.g., soil- and litter-dwelling invertebrates, including earthworms, other micro- and macroinvertebrates, or heterotrophic bacteria and fungi).

Countries outside the U.S. (Canada, Netherlands) have developed various cleanup criteria for soils. Most of these criteria are with respect to groundwater protection although some countries (e.g., Canada) have developed a limited number of soil criteria based on phytotoxicity and animal health (ASTM 1995).

4.4.4.3 Development of Terrestrial RTVs for Wildlife

Two general steps are performed in the derivation of RTVs for terrestrial wildlife: a hazard identification and a dose-response evaluation. A hazard identification is a qualitative assessment that determines whether exposure to a chemical can cause an increase in the occurrence of a particular adverse effect in the key receptors. A hazard identification includes a review of the physical and chemical properties of the chemical, examination of typical routes of exposure, and a review of the toxicologic effects of the chemical (acute, subchronic, and chronic).

When a chemical has been identified as potentially producing adverse health impacts on wildlife, a dose-response evaluation is performed that quantifies the relationship between the dose or exposure to a chemical and the

incidence of adverse effects. The available data are reviewed from a number of viewpoints, and the study or studies that best describe the potential toxicity of the chemical are selected as the basis for deriving a quantitative description of the chemical's toxicity. Uncertainty factors or extrapolation models are commonly applied to transform the dose-response relationship observed in an experimental study to one that can be used to describe potential wildlife exposures to environmental media.

Central to the determination of the RTV is the evaluation of the threshold or exposure level that must be exceeded for the adverse impact of the chemical to manifest itself. Below this threshold, factors such as the body's protective mechanisms (e.g., metabolism, elimination) can handle the chemical, preventing expression of adverse effects. The basis of the derivation of the RTV, then, is to identify this threshold level, and modify it to express potential toxicity to a wildlife population. In deriving the RTV, however, it is important to examine both LOAEL and NOAEL values in order to select the most reasonable endpoint and benchmark value that is protective of the more sensitive receptors without being overly conservative.[14]

Derivation of an RTV for ecological receptors is similar to derivation of a reference dose (RfD) for humans. An RTV may thus be similarly defined as "a provisional estimate of a daily exposure to the ecological receptor population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime, in the case of a subchronic RTV, or during a lifetime, in the case of a chronic RTV" (EPA 1992k).

To develop a chronic RTV, available toxicological studies are reviewed and a critical literature benchmark study (or studies) is selected as the basis for the RTV. Depending on the types of key receptors for the site, literature studies on a variety of organisms may need to be reviewed. The selection of a critical study or studies and their benchmark values is made by professional judgment, but includes consideration of study quality, relevance of the study to wildlife exposures, and other factors. Field studies, as well as laboratory studies are useful in the RTV determinations. Often field studies provide key ecological information showing that while the chemical elicits a toxic response in laboratory studies, it may not necessarily elicit similar results under field conditions. When laboratory studies are used, preference may be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations.

The highest level of exposure associated with the NOAEL or LOAEL is identified (i.e., the literature benchmark value).[15] A NOAEL or LOABL value is preferred over a lethal dose value for calculation of the RTV. In order to compare benchmark values, dietary concentrations (mg/kg) must be converted to dose values (mg/kg-bw), so that dose is not under- or overestimated when applied to organisms consuming different amounts of food per body weight. Average ingestion rate and body weight for a species (and life stage) are reported in relevant studies or may be obtained from various literature sources (EPA 1993e, Appendix B).

Where lacking, chronic NOAEL RTVs may be generated for a species of concern by applying "safety factors" (also called uncertainty or modifying factors) to available toxicity data on a specific COEC. Specific methodologies for deriving RTVs have been published by EPA (1995b), Newell, Johnson, and Allen (1987). and USAERDEC (1994). Application of safety factors represents a specific area of uncertainty inherent in the extrapolation of experimental laboratory data to wildlife and should be evaluated for its eventual impact on risk estimation. To derive an oral RTV, the NOAEL or LOABL may be divided by various uncertainty factors as shown below:

$$RTV = \frac{\text{NOAEL or LOAEL}}{UFs_s \times UF_c \times UF_e \times UF_i}$$

[14] Selection of a conservative literature benchmark value when combined with conservative uncertainty factors can lead to the development of an RTV that is far below that of typical background concentrations (inorganics). Use of such RTVs, when combined with reasonable bioconcentration factors, to estimate intake for lower trophic level receptors sometimes indicates that the background concentrations pose extreme and unrealistic hazards. Caution, accompanied by an appropriate uncertainty discussion, should be used in developing RTVs.

[15] NOAELs and LOAELs ate artifacts of the specific dosing regime employed in the individual toxicity studies and can vary considerably from study to study. Despite the connotations associated with the acronyms, these values do not represent actual threshold levels for toxicity. Therefore, their use in selecting benchmark values or RTVs introduces an additional element of uncertainty.

The uncertainty and modifying factors used by EPA include the following:

- **UF_s = an intertaxon uncertainty factor between 1.0 and 100 for extrapolating toxicity data across test species. Also called a species sensitivity factor (SSF), this adjustment may be necessary where toxicity information does not include representative wildlife species or the species identified as requiring greater protection. If data are from numerous species and represent the most sensitive mammalian and avian species, the SSF may be equal to 1.0. Caution should be taken in using uncertainty factors to extrapolate across widely disparate taxonomic groups; e.g., birds to mammals and vice versa.**

- **UF_c = an uncertainty factor between 1.0 and 10 for subchronic to chronic exposures. This factor may be used when assessing highly bioaccumulative chemicals, where toxicokinetic considerations suggest that a bioassay of limited length may underestimate hazard.**

- **UF_e = an uncertainty factor between 1.0 and 10 for LOAEL to NOAEL extrapolations.**

- **UF_i = an uncertainty factor of 10 for intraspecies toxicological differences to protect, in special cases, sensitive individuals rather than a population. Also called an intraspecies uncertainty factor (ISF).**

Values other than 1.0 (or maximum values) would rarely if ever be used for all uncertainty factors simultaneously (EPA 1995b), as this tends to result in an unreasonably conservative benchmark value. Also, where an intermediate uncertainty factor is to be applied, a value of 3.0, based on a logarithmic scale, can be applied rather than a 5.0, based on a linear scale (EPA 1995b). An additional modifying factor between 0 and 10 may also be applied, if it is judged to be necessary, to account for miscellaneous factors not specifically addressed by the above four uncertainty factors. An example of the process for developing an RTV for a small mammalian receptor is shown in CS 12.

Guidance as to the determination of the magnitude of the numerical value to be assigned to each uncertainty factor is lacking for ERAs. For further guidance on selection of an appropriate uncertainty factor, the risk assessor should consult the regional EPA or DoD (U.S. Army, U.S. Navy) BTAG/ETAG experts. Typically, separate RTVs are developed for large mammals (herbivores/carnivores), small mammals (rodents), and birds.

4.4.4.4 Use of an Acute to Chronic Conversion Ratio

In some cases, chronic toxicity data are not available and an acute/chronic ratio must be applied to acute toxicity data (typically mortality) to estimate chronic effects levels. Because wildlife toxicity databases are fairly limited, use of a factor for extrapolating from acute data to chronic data will likely be large and result in an overly conservative RTV.

4.4.4.5 Short-Term Critical Toxicity Values

Certain exposures, such as during construction or remediation activities, may occur only for a brief time. Likewise, exposure of mobile wildlife to site contamination may be brief and intermittent. These exposures require the use of short-term or acute toxicity values. In most cases, risk assessments are concerned with longer exposures that are appropriately addressed by subchronic or chronic RTVs. Applying these values, however, to very short-term exposures (less than two weeks) may not be valid. Results of primary toxicology studies should be used in evaluating potential effects of short-term chemical exposures. Direct comparisons should be made cautiously, however, because of the limitations of single study results. The uncertainties and assumptions involved in the use of acute RTVs should be clearly stated in the assessment.

4.4.4.6 Feeding and Drinking Rates

When drinking and feeding rates and body weight are needed to express the NOAEL or LOAEL in mg/kg-bw/d, they should be obtained from the literature benchmark study from which the NOAEL or LOAEL was derived. As noted earlier, dietary chemical concentrations in mg/kg must be normalized for body weight and food intake of the test organism and receptor of concern before they can be used as a screening benchmark.

Depending on the organism and study, dry weight chemical concentrations may also need to be converted on a wet-weight basis. Use of wet weight versus dry weight in estimating dietary exposures can be problematic, particularly where the moisture content of the diet is highly variable (e.g., in plants). Dietary concentrations in most toxicological studies are reported on a wet-weight basis. However, moisture content of laboratory diets is

CASE STUDY 12

DERIVATION OF A SMALL MAMMAL RTV FOR ACETONE

The following describes the process for deriving a site-specific reference toxicity value (RTV), in this case for small mammal receptors that ingest site soil.

Selection of Literature Values

The toxicological data for acetone are assembled from available literature sources and screened to select the lowest LOAEL and highest NOAEL literature values (mg/kg-bw/day) for chronic (long-term) effects, if available.

The literature values collected are shown below:

TOXICITY DATA FOR ACETONE

Test Species	Form	Duration	Effect level/Effect	Dietary (mg/kg-food)	Dose (mg/kg-bw/day)	Reference
MAMMALS						
Rat	–	13 weeks	NOAEL/ respiratory, cardiovascular, gastrointestinal, musculoskeletal, hepatic, dermal, body weight effects	–	3,400	NTP 1991, Dietz et al. 1991
Rat	–	14 days	LOAEL/bone marrow hypoplasia	–	6,942	NTP 1991, Dietz et al. 1991
Rat	–	14 days	NOAEL/hepatic, renal, body weight effects	–	8,560	NTP 1991, Dietz et al. 1991
Rat	–	13 weeks	LOAEL/reproductive effects	–	3,400	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	NOAEL/renal, body weight effects	–	12,725	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	LOAEL/hepatic effects	–	3,896	NTP 1991, Dietz et al. 1991

LOAEL - Lowest observable adverse effects level
NOAEL - No observable adverse effects level

Reference Toxicity Value

Each selected literature value is then divided by a conservative total uncertainty factor to calculate a long-term RTV that is used to screen measured surface soil and dietary concentrations in order to determine whether acetone may need to be evaluated further. The total uncertainty factor is the product of one or more separate uncertainty factors for each of two sources of uncertainty: (1) study duration and (2) study endpoint. Within the study endpoint category, two toxicity test endpoint categories are listed: nonlethal effects (e.g., a change in fecundity) and lethal effects (i.e., some level of reported mortality). A frank effect level is the concentration of a chemical that causes an obvious deleterious effect; the lethal frank effect level is the LD_{50} concentration (a concentration or dose that is lethal to 50% of animals in the study). The uncertainty values assigned to each category are described below:

UNCERTAINTY FACTOR PROTOCOL FOR LONG-TERM REFERENCE TOXICITY VALUES

Basis for Uncertainty		Uncertainty Value Assigned
Study Duration Category		
Chronic studies where contaminants attained equilibrium		1
Chronic studies where equilibrium not attained or possibly not attained, including subchronic studies		5
Acute studies (7 to 14 day, 2 to 7 day, 1-day single dose)		10, 15, 20
Study Endpoint Category**	Nonlethal	Lethal
No observed effects level	NOEL: 1	NOEL: 3
No observed adverse effects level	NOAEL: 1	NOAEL: 3
Lowest observed effects level	LOEL: 3	LOEL: 10
Lowest observed adverse effects level	LOAEL: 5	LOAEL: 10
Frank effects level	FEL: 10	FEL: 15

** To estimate an appropriate NOAEL

REFERENCE TOXICITY VALUES

A summary of the information used to derive the RTV for acetone is presented next. The two uncertainty factors most applicable to the toxicological study were selected, combined, and then divided into the selected literature value. The resulting RTV dose (mg/kg-bw/day) is used in the conservative risk screening for comparison to the site-specific surface soil dose (mg/kg-bw/day) to determine if acetone may need further evaluation.

LONG-TERM REFERENCE TOXICITY VALUES

Chemical (COC)	Species	Literature Value: Dose (mg/kg-bw/day)	Literature Value: Effect Level	Study Duration Uncertainty	Study Endpoint Uncertainty	Total Uncertainty Factor	Reference Toxicity Value (RTV) (mg/kg-bw/day)
Acetone	Rat	3400	NOAEL	5	1	5	680

also typically less than 10 percent, so this difference is sometimes ignored (Beyer and Stafford 1993). The risk assessor should, at a minimum, strive to be consistent (or conservative) in reporting between wet weight when comparing the RTV to the exposure intake value in the risk calculation. The basic equation for converting tissue analyte concentration between dry and wet weight samples is

Wet weight tissue concentration = dry weight tissue concentration x (% solid/100).[16]

where % solids = 100 - % moisture

If the literature benchmark study does not provide the needed values, they should be determined from appropriate data tables for the particular study species. For studies done with domestic laboratory animals, RTECS (NIOSH 1987 or latest edition) can be consulted. When insufficient data exist for other mammalian or avian species, the allometric equations from Calder and Braun (1983), Nagy (1987). and EPA (1988k, 1993e) can be used to calculate feeding and drinking rates (Exhibit 15). Reference food and water intake values for a variety of wildlife are also provided in ORNL (1994).

4.4.5 Additional Considerations in Developing RTVs

There are a number of additional factors that should be considered when conducting the effects characterization, reviewing the toxicological literature, and determining RTVs. These are discussed in the following sections.

4.4.5.1 Absorption Considerations

Most toxicity values are based on administered, rather than absorbed, doses, and the absorption efficiency has not been considered. However, whatever absorption has occurred during the toxicological study is inherent in the toxicity value. Therefore, use of a toxicity value assumes that the extent of absorption observed in the study is also appropriate for the exposure pathway being assessed. Differences in absorption efficiencies between that applicable to the RTV and that being assessed may occur for a number of reasons. Two factors that will influence absorption efficiencies are differences in chemical form and differences in the exposure medium.

The form of the chemical used in the literature benchmark wildlife study may not be the same as the chemical form present in the environmental medium being assessed, and may be absorbed to a different degree. Therefore, use of the toxicity value may over- or underestimate the actual absorption potentially occurring in receptors. This is especially important for certain metals where inorganic forms (e.g., metallic lead) differ widely from organic forms (e.g., lead acetate) in their potential toxicity. The basis of the chemical's RTV should be reported in the effects characterization and compared with the form (if known) in the site media. Often the form in site media is not known, but can sometimes be inferred based on site history or by the medium in which the chemical is found (for example, a metal in soil is unlikely to be present in its soluble form).

In toxicity studies, chemicals are often administered in drinking water, mixed with food, or mixed in an administration vehicle such as olive oil to facilitate absorption. In environmental settings, exposure to chemicals may occur in a medium similar to that used in the study (e.g., in drinking water) or in a medium quite different from that used in the study (e.g., the soil matrix). Certain media, particularly soil and sediments, may bind chemicals, reducing the amount that is available for absorption (i.e., bioavailability). In these instances, it may be appropriate to reduce the COEC intake value in the exposure calculation with a matrix effects or bioavailability factor to account for this binding (see Section 4.3.3.3.5).[17]

[16] Given a 230-mg/kg wet weight of lead in plants and a 20% moisture content, the dry weight concentration would be 287.5 mg/kg.

[17] Numerous studies show that not only metals but organic chemicals, including pesticides, bind tightly to soil, reducing their bioavailability through both oral and dermal exposure. Calderbank (1989) showed that clays and organic colloids have a large surface area and cation exchange capacity, which permit significant adsorption of virtually all classes of pesticides: furthermore, the adsorbed fraction (20% to 70%) desorbs slowly and is effectively a bound fraction that increases over time as the soil-pesticide bond "ages." Shu et al. (1988) reported a bioavailability range of 25 to 50% for TCDD to rats from soils at Times Beach, Missouri. Goon et al. (1991) showed that benzo(a)pyrene (BaP) that had aged 6 months in soil was only 34 and 51% orally bioavailable for clayey and sandy soils, relative to BaP administered alone to rats. In general, differences in absorption between lab media and site media should not be assumed, unless there's adequate information to the contrary.

4.4.5.2 Assessment of inhalation Exposure Route for Wildlife

Inhalation exposure routes are generally not addressed in ERAs due to the lack of toxicity information for wildlife species and the lesser significance of the inhalation exposure route to the oral ingestion route." In general, VOC concentrations of 100 ppm or greater in air are needed to induce toxic responses in laboratory rats and mice from inhalation (NIOSH 1987). Concentrations in soils would have to be many times greater than this to produce these toxic levels in air, even near the soil surface.

In order to quantitatively evaluate this exposure route, the risk assessor may need to consider factors such as the target species' airway size, branching pattern, breathing rate (volume and frequency), and clearance mechanisms, whether the contaminant is a gas or aerosol, whether the chemical's effects are systemic or confined to the respiratory tract, as well as particle size distribution, temperature, and vapor pressure, and pharmacokinetic data (EPA 1993e). In addition, the dose deposited, retained, and absorbed in the respiratory tract is a function of species anatomy and physiology as well as physicochemical properties of the contaminant, Allometric equations are available from EPA (1993e). A procedure for calculating inhalation exposure is also published by USDOI (1991).

Total petroleum hydrocarbon (TPH) contamination is one example where the inhalation of volatiles for small, burrowing animals is of concern in the ERA. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via inhalation and dermal exposure pathways for benzene, toluene, ethylbenzene, total xylenes (BTEX), and PAHs. These methodologies may be applied where site-specific conditions require inhalation exposure to be considered an important exposure route. The methodology for calculating inhalation concentrations for humans as discussed in EPA's (1990e) *Interim Methods for Development of Inhalation Reference Concentrations* may be followed to some extent.

[18] A notable exception is the great number of studies conducted on response and uptake by birds and mammals from aerial pesticide spraying on agricultural crops.

4.4.5.3 Assessment of Dermal Exposure Route for Wildlife

Dermal exposure routes are generally not addressed in ERAs due to limited toxicity information for terrestrial wildlife species and the lesser significance of the dermal exposure route to the oral ingestion pathway. The dermal pathway may be of importance where wildlife are directly sprayed or frequent areas with surface-contaminated vegetation or where the animals are burrowing in contaminated soils/sediments.

Wildlife are generally assumed to be protected by their fur, feathers, or scales, which prevent a chemical from reaching an animal's skin and may allow the chemical to dry or to be rubbed off during movement. Dermal absorption of contaminants is a function of chemical properties of the contaminated medium, the permeability of the receptor's outer covering, area in contact with the contaminated medium, and the duration and pattern of contact. The methodology for calculating dermal exposure concentrations for humans is discussed in EPA's (19921) *Dermal Exposure Assessment: Principles and Applications* and may be followed to some extent where dermal exposure concentrations for wildlife need to be calculated.

Dermal exposures may be of concern for wildlife that swim or burrow. Mammals and birds groom themselves regularly and may receive an oral ingestion dose from dermal contamination of their fur or feathers. An oral ingestion dose for animals which groom themselves may be calculated based on a methodology published by USDOI (1991) for determining dermal exposure to representative western rangeland wildlife species from herbicide sprays. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via dermal exposure pathways for BTEX and PAHs. Such a methodology may be applied where site-specific conditions require dermal exposure to be considered an important exposure route.

4.4.5.4 Body Scaling Factors

In the ORNL (1994) document, body scaling factors are applied to derive screening toxicity benchmark values for various sized organisms, based on a select reference

toxicity value. Application of a 2/3 or 3/4 exponential factor for wildlife is based on the human health practice of applying an exponential factor of 2/3 in adjusting animal data to an equivalent human dose. Wildlife toxicologists, however, commonly scale dose to body weight when deriving benchmark values without incorporating this exponential factor.

4.4.6 Special Chemicals

Some commonly detected chemicals require special consideration in the generation of an RTV (e.g., their potential to biomagnify, need for a surrogate component evaluation, difficulty in obtaining toxicity information) or have specific chemical forms that greatly influence bioavailability and toxicity. The following chemicals are discussed in this light:

- Metals.
- Polycyclic Aromatic Hydrocarbons (PAHs).
- Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBs).
- Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs).
- Total Petroleum Hydrocarbons (TXH) and other petroleum groupings.
- Military chemicals.

4.4.6.1 Metals

The toxicity of metals depends foremost on chemical form. For example, chromium (+3) occurs naturally and is common in the environment and has a relatively low toxicity. Chromium (+6) is largely related to anthropogenic releases and is very toxic, but is readily reduced in the environment to chromium (+3). Organometallic forms (methylmercury, alkylead) are more toxic than the elemental forms. Much of the literature does not specify the chemical form of an element when discussing its toxicity to biota. It may be assumed in these instances that only the total concentration of the metal was known.

To be toxic an element must be available to the receptors. In order for this to occur, the chemical must exist in a form that can enter tissues of the organisms. Total amounts of a chemical in the environment are not relevant to an adequate estimation of toxicity hazard unless it can be shown that the element exists in, or is likely to assume, an available form under the environmental conditions in which it occurs, and animals or plants are likely to contact this form either directly or indirectly (Gough, Shacklette, and Case 1979).

Aquatic Organisms and Metals

The site-specific toxicity of a metal to aquatic organisms depends on the physical form of the metal, the effect of other metals and organic compounds (anthropogenic and naturally occurring) in the water, as well as the chemical or ionic form of the metal of interest. Metals results from surface water analyses can be reported in terms of the total recoverable metals, total metals, acid soluble metals, or dissolved metals. All four methods measure all of the dissolved metal present but differ (because of varying field or laboratory procedures) in the amount of particulate metal measured. While Federal AWQC are reported as total recoverable metals, many states have standards based on dissolved metals. The basis and form (dissolved versus total) of the specific criteria should be verified before being applied at a site. The risk assessor may also need to take into account transformation of onsite metals to bioavailable forms with migration offsite.

In order to develop a better understanding of metals criteria, bioavailability, and toxicity, EPA has issued a series of guidance documents (EPA 1992j; 1993c; 1995f) to supplement the *Water Quality Handbook* (EPA 1993g). These documents describe:

- Relationships among the various physical forms reported in water quality results.
- The importance of site-specific bioassays (if this level of effort is justifiable) to create a WER to account for the fact that in situ metals toxicities are frequently less than reported from laboratory bioassay tests.
- Observed ratios between dissolved metals and total recoverable metals in order to facilitate interpretation of AWQC and the more bioavailable dissolved metals.

Plants and Metals

Plants are intermediate reservoirs through which trace metals from primary sources move to other living things. Plants may be passive receptors of trace metals, as in root adsorption, or they may accumulate and store metals in nontoxic forms for later distribution and use (Tiffin 1977). A mechanism of tolerance in some plants apparently

involves binding of potentially toxic metals at the cell walls of roots and leaves, away from sensitive sites within the cell. The metal forms which occur in plants appear to have a decisive role in metal transfers to other organisms (Tiffin 1977).

There are a large number of processes that operate to regulate metal cycling, including ion exchange, adsorption, formation of organic complexes, and precipitation. All these have different and often opposing effects: and all are very dependent on pH and other soil/sediment characteristics. Since site conditions vary so much in these respects, both spatially and temporally, metal reactions and fates often vary. In addition to environmental variability, there are differences due to plant physiology and genotype (Outridge and Noller 1991). Therefore, it is very difficult to extrapolate from one study location or plant to another.

As described in Dunbabin and Bowmer (1992) there are some general trends that have been noted. Potential bioavailability generally increases with increases in acidity, reducing power, salinity, and concentration of organic ligands. However, if sulfur is present, a reducing environment will result in the production of insoluble metal sulfides. Other specific factors that influence bioavailability include sediment size (clay provides more surface area for adsorption and reactions), presence of hydrous iron and manganese oxides (which adsorb metals), and the nutrient regime (which, for example, affects the ability of microbes to transform elemental mercury to methylmercury) (Stewart, Haynes, and Martinez 1992).

Terrestrial Fauna and Metals

Several metals, while potentially toxic, are also essential micronutrients for plants and animals, e.g., zinc, selenium. All metals, whether essential or nonessential, can adversely affect terrestrial organisms, if included in the diet at excessively high levels. In general, tolerance levels vary from animal to animal and even from day to day in a single animal (NAS 1980). Many factors, such as age and physiological status of the animal (growth, lactation, etc.), nutritional status, levels of various dietary components, duration and route of exposure, and biological availability of the compound, influence the level at which a metal may cause an adverse effect in the organism (NAS 1980). Exposure of animals to excessively high concentrations of metals can result in acute signs of toxicosis, which may be quite different from the chronic effects displayed after the metal has been ingested at higher than normal levels over an extended period of time. Metals that biomagnify (e.g., mercury, selenium) require the application of food chain multipliers (BAFs or BMF) to concentrations in prey organisms for higher trophic level predators. Concentrations of inorganic metals in a BAF or BCF study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the substance is a micronutrient (e.g., selenium), while still below levels which adversely affect the species (EPA 1995b).[19] Bioaccumulation of inorganic metals may be inappropriately overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms (EPA 1995b).

4.4.6.2 Polycyclic Aromatic Hydrocarbons (PAHs)

PAHs, also known as polynuclear aromatic hydrocarbons, or polynuclear aromatics, PNAs, are a class of compounds containing hydrogen and carbon in multiple ring structures. There are numerous possible PAH molecules, several of which are common analytes in a semivolatile compound analysis. PAHs are natural components of petroleum and are found in heavier petroleum fractions, such as lube oil, naphtha, etc. PAHs are also produced by the incomplete combustion of organic matter. For this reason, PAHs are ubiquitous in the environment at low levels, particularly in soil and sediments, to which they readily bind.

In general, PAHs are rapidly metabolized and considered unlikely to biomagnify despite their high lipid solubility (Eisler 1987). Inter- and in&a-species responses to individual PAHs are quite variable, however, and are significantly modified by many inorganic and organic compounds (Eisler 1987). Until these interactive effects are clarified, extrapolation of laboratory test results to field situations where there is suspected PAH contamination should proceed cautiously. The intermediate metabolites, however, have been identified as mutagenic, carcinogenic, and teratogenic agents (Sims and Overcash 1983). In most cases, the process of carcinogenesis occurs over a period of many months in experimental animals, although for some PAHs, malignancies may be induced by acute exposures to microgram quantities.

---

[19] Cam should be taken in using partitioning models to estimate BCFs or BAFs for soil-dependent organisms such as earthworms and plants. Models based on diffusivity constants and anaerobic conditions can result in unrealistically toxic concentrations (>1 percent) in the soil organism.

Amphibians are reported as quite resistant to PAH carcinogenesis when compared to mammals due to the amphibian's inability to produce mutagenic metabolities of BaP and perylene (Anderson, Doos, and Rose 1982). The ability to metabolize PAHs in nonmammalian species, however, is extremely variable and cannot be predicted on the basis of phylogenic associations. When PAHs are not metabolized, they have been shown to bioaccumulate and therefore pose a significant dietary route of exposure to predatory species. In species which can metabolize PAHs, one significant mode of toxicity is impairment of reproductive cycles.

Small mammals which burrow and ingest soil are likely to be the ecological receptors with the greatest potential exposure and risk from PAHs. Data are generally lacking on the acute and chronic toxicity of PAHs on avian wildlife (Eisler 1987). Eisler (1987) reports PAHs show little tendency for bioconcentration or biomagnification, particularly in terrestrial ecosystems, probably because most PAHs are rapidly metabolized. Beyer and Stafford (1993) also found PAH concentrations in earthworms to be well below soil levels. Gile, Collins, and Gillet (1982). however, report fairly high bioaccumulation factors for terrestrial species. In their 3-month mesocosm experiment using creosote coal tar distillate (which contained 21% phenanthrene and 9% acenaphthene), PAH concentrations in various animals were found to be elevated over average PAH soil concentrations.

PAHs can accumulate to some extent in terrestrial plants. Atmospheric deposition on leaves, however, is likely to be a more significant pathway than uptake from soil by roots (Vaughn 1984). Uptake of PAHs by plant roots is dependent on numerous factors including concentration, solubility, molecular weight of the PAH, and on the plant species (Edwards 1983).

4.4.6.3 Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBsl

OCPs and PCBs are extremely stable compounds and slow to degrade under environmental conditions. The toxicoiogical properties of individual PCBs and pesticides are influenced primarily by two factors: the partition coefficient, (K_{ow}), based on solubility in n-octanol/water, and stearic factors, resulting from different patterns of chlorine substitution. The more highly chlorinated forms of PCBs and pesticides tend to be more persistent, more strongly sorbed, less volatile, and less bioavailable (O'Connor, Chaney, and Ryan 1990, Sawhney 1988, Strek et al. 1981).

PCBs and pesticides are strongly sorbed in soils, sediments, and particulates in the environment, with levels usually highest in aquatic sediments containing microparticulates (Eisler 1986, EPA 1980, Duinker, Hillebrand, and Boon 1983). PCB and pesticide uptake from contaminated soils and sediments is governed by processes that include both direct incidental ingestion of contaminated soil/sediment particles and indirect ingestion via food webs or from parents to the fetus or embryo. Toxicity reports based on plant (terrestrial) uptake of pure PCBs and pesticides can be misleading because these chemicals are often added to the exposure medium at unreasonably high concentrations to facilitate analysis or they are added to coarse-textured soils extremely low in organic matter (O'Connor 1989).

PCBs, dioxins, and pesticides are all highly lipophilic, with the greatest concentrations occurring in fatty tissues. PCBs, dioxins, and pesticides are of greatest concern to higher trophic level predators. In mammals, these chemicals are readily absorbed through the gut, respiratory system, and skin, and can be transferred to young mammals either transplacentally or in breast milk. In birds, particularly endangered raptors, a reduction in eggshell thickness has been the endpoint of greatest concern from pesticides. Evidence implicating PCBs as a major source of eggshell thinning is inconclusive (Eisler 1986, Wiemeyer et al. 1984, Henny et al. 1984, Norheim and Kjos Hanssen 1984). Consideration of the potential bioaccumulative effects of PCBs, dioxins, and pesticides is important in the selection of appropriate assessment and measurement endpoints.

4.4.6.4 Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs)

CDDs/CDFs, often abbreviated "dioxins and furans," are a group of chlorinated compounds based on the dibenzo-p-dioxin or dibenzofuran molecule (the two of which are structurally similar). CDDs/CDFs are not compounds used for commercial purposes in the past, and, outside of research, have no known use. Rather, CDDs/CDFs are byproducts of high temperature combustion of chlorinated compounds and impurities in other chemical products such as pentachlorophenol (CDDs) or polychlorinated biphenyls (CDFs). Although not considered a "natural" product, some forms of CDDs and CDFs (specifically octa-CDD and octa-CDF) are ubiquitous in the environment at very low concentrations.

There are 75 possible CDD congeners and 135 possible CDF congeners. As with PCBs, the degree of toxicity

varies with the degree and location of chlorination, becoming greatest when the 2, 3,7, and 8 positions of the molecule are substituted. The 2,3,7.8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is considered the most potent CDD, and is the reference against which all other CDDs and CDFs are compared.

Analysis of CDDs and CDFs is most commonly reported by congener group (i.e., as either tri-, tetra-, penta-, hexa-, hepta, or octachlorodibenzop-dioxin or dibenzofuran). Within these groups, the results are often further separated into "2,3,7,8- substituted" or "other" categories. This form of reporting is needed to appropriately assess CDDs and CDFs. Reporting as "total dioxins" or even just by congener group may require the assumption that all CDDs/CDFs present are as toxic as 2,3,7,8-TCDD, resulting in an overestimate of potential risk posed by the presence of CDDs/CDFs.

Piscivorous fish and wildlife are thought to be particularly at risk from these chemicals due to their large exposure through aquatic food chains. The limited available toxicological data indicate that fish, especially salmonid sac fry, and mink *(Mustela vison)* are among the most sensitive animals to TCDD and related compounds. A recent assessment of the toxicity of these compounds along with environmental concentrations associated with TCDD risk to aquatic life and associated wildlife has been released by EPA (1993h).

Two basic methods are recommended for evaluating the toxicity of mixtures of PCBs, PCDFs, and PCDDS in environmental samples to determine sample "toxic equivalents" relative to TCDD (EPA 1993h). In the first method (commonly used in screening ERAs), individual PCB (Section 4.4.6.3), PCDF, and PCDD congeners are determined and multiplied by toxic equivalent factors (TEFs) to express potential toxicity in TCDD-equivalents (EQs). In the TEF approach for CDDs/CDFs, the toxicity of the TCDD compounds is expressed relative to the toxicity of 2,3,7,8-TCDD for mammalian systems (Safe 1990. Ankley et al. 1992). Soil or prey tissue doses of dioxins/furans may be calculated by applying congener-specific TEFs to the concentrations of the dioxins or furans prior to conversion of concentrations to doses. TEFs, however, are a species-specific construct and the TEF multipliers vary widely among species, depending on their ability to metabolize specific congeners. TEFs recommended by EPA (1995b) and Safe (1990) are frequently used in screening ERAs (see Exhibit 17). Recent publications (Newsted et al. 1995) presenting TEFs for fish should be considered for preferential use in aquatic risk assessments.

In the second method, the total PCB/PCDF/PCDD mixture is extracted from the environmental samples and then tested for potency, relative to TCDD, using a standard biological response (rat hepatoma cytochrome induction) as an endpoint (EPA 1993h). This latter approach bypasses the assumption of an additive model of toxicity for complex mixtures. If the latter biological approach for measuring TCDD-EQ is to be used for quantitative risk assessment, it is important to calibrate the biological system used with specific toxicological endpoints in the receptors of concern (EPA 1993h). Further discussion of TEFs for CDDs/CDFs can be found in *Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin Risks to Aquatic Life and Associated Wildlife* (EPA 1993h). EPA's (1994g) dioxin wildlife workshop report, and in the GLWQI (EPA 1995b).

4.4.6.5 Total Petroleum Hydrocarbons (TPH) and Other Petroleum Groupings

TPH are common contaminants at DoD sites. Petroleum hydrocarbons originate from a variety of petroleum-derived fuels including jet fuel, fuel oils, and gasoline. Determination of the actual source material (gasoline versus fuel oil) is not always possible, particularly where site history is unknown. Composition of any given fuel will also vary depending on the source of the crude oil, refinery processes, and product specifications. Also, due to differential volatilization and biodegradation, the composition of the original fuel mixture in the environment is altered over time. Therefore, the toxicity of the insoluble and nonvolatile components remaining some time after a spill is often of more interest than volatile compound toxicity.

Because of the originally unknown and potentially altered composition of the spilled fuel, TPH toxicity is frequently assessed based on individually measured constituent toxicity, rather then by assessing the measured TPH concentration as a whole mixture. The primary constituents of petroleum components, such as paraffins and naphthenes, are generally not considered to be highly toxic (Amdur et al. 1991; Clayton and Clayton 1981) and are typically not included as COECs in ERAS. Aromatic constituents such as benzene and xylene and the carcinogenic PAH compounds are the primary COECs for risk assessments. Noncarcinogenic compounds, such as toluene, ethylbenzene, xylenes, naphthalene, and other noncarcinogenic PAH compounds, may be of concern for potentially acute toxic effects.

The impacts of TPH on terrestrial ecosystems are not as well documented as the impacts on aquatic ecosystems.*' Some attempts have been made in human health risk assessment to derive critical toxicity values for TPH. However, since the composition of TPH varies from place to place (even within the same site) as well as change in time (fresh versus aged product), it is unlikely that using critical toxicity values for this group of chemicals pro vi&s valuable descriptors of the potential toxicity of the components comprising the TPH detection. The BTEX and PAH compounds are currently used in characterizing potential risks and cleanup requirements for TPH because these chemical groups include the most toxic known TPH constituents and represent a broad range of physical and chemical properties influencing environmental mobility.

4.4.6.6 Military Chemicals

Many DoD sites contain potentially toxic chemicals not commonly found on nonmilitary sites. Military-specific chemicals may include explosives, rocket fuels, radioactive materials, chemical agents, or degradation products of these compounds. Because of the unique status of many military compounds, EPA is often unable to supply toxicity information. Profiles containing toxicological information relevant to an ERA can be obtained from USACHPPM and USAEC.[21] Technical reports that summarize environmental fate and behavior (plant uptake, mammalian and aquatic toxicology) of munitions material are also available in the open literature (Burrows et al. 1989, Cataldo, Harvey, and Fellows 1990, Layton et al. 1987). Pertinent information can also be obtained from site-specific environmental studies at installations such as Joliet AAP and Rocky Mountain Arsenal and by contacting the regional EPA or U.S. Army BTAG/ETAG **persons.** Appendix F presents several ecotoxicological profiles on military chemicals.

[20] The American Petroleum Institute (API) lists numerous reports regarding TPH toxicity in aquatic ecosystems. Effects concentrations in water for various oil products (bunker, crude, diesel, gasoline, jet fuel, lube oil), taxonomic group (invertebrates, fish, algae), and presence/absence of free product can be found in *A Critical Review of Toxicity Values and an Evaluation of the Persistence of Petroleum Products for Use in Natural Resource Damage Assessments,* API, April 5, 1993.

[21] Contacts for toxicity information on military chemicals: USAEC (Mr. Robert Muhly @ 410-612-6839 and Ms. Mary Ellen Maly @ 410-671-1523); USACHPPM (Dr. Glen Leach @ 410-671-3980).

4.4.6.7 Toxicologic Uncertaintles

Use of EPA-derived aquatic and wildlife toxicity values should be examined with regard to the degree of uncertainty associated with their development. The uncertainties associated with the values should be stated in the effects characterization, and the impact of applying the value estimated, specifically (when the assessment is complete) for chemicals that are major contributors to overall site risks and hazards. The following factors should be addressed:

- What are the cumulative uncertainties and modifying factors applied to derive the RTV?
- Is the form of the chemical used in derivation of the toxicity value the same or similar to that in the environmental medium being assessed?
- Is the duration of the toxicological benchmark study relevant to the exposure conditions for the key receptors being assessed? Actual exposure durations for key receptors may or may not exceed the test duration periods on which the RTVs are based.
- Was the medium applicable to the toxicological study used to derive the toxicity value (e.g., the chemical was administered to the test animal in food, water) similar to the medium being assessed? Could matrix effects or water effects be important in bioavailability?
- Has any route-to-route extrapolation been performed? Was it reasonable to do so, and were assumptions used in the extrapolation appropriate?
- Were surrogate toxicity values (toxicity values for other chemicals that are structurally and/or chemically similar) used for chemicals that do not possess values? Was this approach reasonnable?
- Were BCFs or BAFs applied in the development of the RTV? BAFs and BCFs developed for one study may be quite different than bioaccumulation factors at other areas.

The potential exists for wildlife species to be more or less sensitive than laboratory test species and the derived toxicological benchmarks. Toxicity benchmark values for laboratory organisms may be substantially lower than

those for wildlife due to the sensitive strains of laboratory animals used, the direct means by which they are dosed, and the need to obtain a satisfactory toxic response. The LD_{50} studies are usually designed to promote maximum exposure (absorption) because less of the chemical complexes with dietary material. The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested, while NOEL levels from longer studies are the best (still imperfect) laboratory studies to be used as predictors of field effects. On the other hand, laboratory species may be less sensitive than their wild counterparts in that they must be hardy enough to be amenable to culturing in a laboratory setting or endure animal husbandry and handling.

In contrast to laboratory tests of terrestrial organisms, laboratory tests of aquatic invertebrates or fish show that the tested chemicals may be less toxic to the same or similar animals under natural conditions. This is because the tested chemical is not as bioavailable in natural waters due to the modifying effect of other water quality characteristics (e.g., pH, hardness, suspended solids). In order to estimate the toxicity of a chemical under natural conditions (a Tier II or higher effort), a parallel series of toxicity tests are run using site water and laboratory test water as dilution water and then calculating a WER (site water LC_{50}/lab water LC_{50}).

4.5 Risk Characterization

Risk characterization includes two major steps: risk estimation and risk description (EPA 1992a). The risk estimation consists of comparing the exposure and toxicity profiles, as well as estimating and summarizing the associated uncertainties and assumptions to characterize current and potential adverse biological effects posed by the COECs. The potential impacts from all exposure routes (direct contact, ingestion, and inhalation) and all media (water, sediment, soil, and air) are included in this evaluation as appropriate according to EPA guidance (EPA 1989c). The risk description consists of a summary of the results of the risk estimation and uncertainty analysis and an assessment of confidence in the risk estimates through a discussion of the weight of evidence. The risk description can also include a discussion of additional data or analyses that might reduce the uncertainty in the risk estimates. These additional data collection efforts or analyses would be conducted in subsequent tiers.

4.51 Risk Estimation

In Tier I, risk estimation can be either qualitative or quantitative, depending on the data available, DQOs, and the stated level of effort. Typically, the Tier I risk estimation is performed through a series of quantitative quotient calculations that compare exposure values with RTVs. The RTVs, as derived from literature benchmark values, serve in this case as surrogate measurement endpoints. Simple ratios of exposure values to RTVs are known as HQs which are summed (where appropriate) for all chemicals and exposure pathways for a given receptor to pro vide the HI. The HI method is described below. Quantitative risk estimation techniques can be fairly simple or more complex, depending on the complexity of the food webs and exposure pathways that are to be quantified. Other quantitative approaches that are used in the higher tiers include comparing probabilistic distributions of effects, and exposure and simulation modeling.

Characterization of adverse effects on key receptor species at the population, community, or ecosystem level is generally more qualitative in nature than characterizing human risks. This is because the toxicological effects of most chemicals am not well documented for most species. RTVs that are usable and applicable for the evaluation of ecological effects in ecosystems are generally limited. In the estimation and characterization of risk, the adverse effects of chemicals on populations and habitats should be considered rather than the effects on individual members of a species according to EPA guidance (1989c, 1989a), except in the case of threatened and endangered species, where individuals require protection in order to preserve the population. True risk estimation, therefore, also involves interpretation of results, with professional judgment, to provide the ecological implication of the observations, made at the level of the measurement endpoint. In some cases, this may involve a great deal of professional judgment. In others, the ecological implications are either obvious or inherent due to the level of the chosen measurement endpoint.

4.51.1 Objectives

Most ERAs and nearly all Tier I ERAs provide a comparison of single effect values (RTVs) with predicted or measured exposure concentrations for one or more key receptors. In risk estimation, the chemical intakes

calculated in the exposure characterization are combined with the appropriate critical toxicity values identified in the effects characterization. The results are the estimated ecological hazards posed by the exposures. This ratio or quotient of the exposure value to the effects value (i.e., RTV) provides the risk calculation. Along with the numerical calculations (quotients) of potential ecological risks (hazards), a narrative describing the primary contributors to ecological risks and factors qualifying the results is presented.

4.5.1.2 Ecological Evaluation Techniques

A variety of ecological evaluation tools, techniques, or approaches may be used to evaluate and estimate the magnitude and importance of the risk. Such techniques vary in level of effort, sophistication, and cost, but the most sophisticated or time-consuming techniques are not necessarily the most appropriate to a given site. Many of these evaluation techniques are more appropriately conducted as part of a Tier II, III, or IV effort (see Sections 5.0 through 7.0). Assessment of chemical effects on key receptors is directly dependent on the use of evaluation techniques appropriate for the assessment and measurement endpoints. Decisions as to which techniques to use should be well-documented and follow HTRW *Technical Project Planning Guidance* (USACE 1995b).

Each of the evaluation techniques has its own unique advantages and disadvantages in terms of the data and information provided. Some of these tools are useful to measure effects at the individual operable unit and species level: e.g., field sampling of tissue residues. Tools, such as Habitat Evaluation Procedures (HEP) (USFWS 1987) and Index of Biological Integrity (IBI) (Karr et al. 1986) can be used to quantify injury to biological resources at the community/ecosystem level by measuring reductions in habitat quality. Others such as toxicity tests are used to characterize cumulative hazards from multiple chemicals with no attempt to apportion chemical contribution from the individual OUs or to discern mechanisms of chemical interactions. Tools such as probabilistic pathways analysis are most appropriate when there is an endangered species at risk from chemicals that bioaccumulate. To measure critical ecosystem functions such as nutrient cycling, tools other than those listed may be needed.

Each technique has its own peculiarities in terms of the interpretation of results, and many of these tools cannot account for such phenomena as biological resistance. Also, some of these tools are restricted as far as their applicability (e.g., Wetland Evaluation Technique [WET] and the sediment-water equilibrium partitioning approach may only be used in wetlands). No single species test, indicator parameter analysis, statistical procedure, or field inspection review can address the complex nature and extent of contamination or risk in biological systems. Impacts at one hierarchal level do not always translate easily into effects at other levels, and emergent system-level properties cannot be studied at lower levels of organization (Kimball and Levin 1985). Chains of influence are common features of ecosystems, and indirect effects, which can be more important than direct effects, often predominate in ecosystems (Kimball and Levin 1985, Johnson et al. 1991). To thoroughly evaluate ecosystem risk, multimedia (i.e., air, water, soil, sediment, and biota) as well as different trophic and hierarchal (organism, community, population, ecosystem) levels may all need to be addressed or measured.

Examples of some ecological valuation techniques and tools (and references where descriptions of the approach may be found) include:

- HQs and HIs.
- Sediment-Water Equilibrium Partitioning (EP) or Water Quality Approach (Long and Morgan 1990).
- Evaluation of Dredged Material Proposed for Ocean Dumping (EPA 1991g).
- Screening Level Concentration Approach (Long and Morgan 1990).
- Apparent Effects Threshold (AET) or Species Approach (Long and Morgan 1990).
- Bioeffect/Contaminant Co-Occurrence Analyses (COA) Approach (Long and Morgan 1990).
- Sediment Quality Triad Approach (Chapman 1989).
- Rapid Bioassessment Protocols for Use in Streams and Rivers (EPA 1989j).
- Sediment Quality Criteria Approach (Chapman 1989).
- Bioassay Approach (Toxicity Tests) (EPA 1989c).
- Diversity Indices (Pielou 1975).

- Species Richness/Relative Abundance Indices.
- WET (USACE 1987).
- IBI (Karr et al. 1986).
- HEP (USFWS 1987).
- Exposure Pathway Analysis (Fordham and Reagan 1991).
- Probabilistic/Sensitivity/Uncertainty Analysis (Macintosh. Suter, and Hoffman 1994).
- Linear Structural Modeling (Johnson, Huggins, and DeNoyelles 1991).
- Linked Deterministic and Simulation Models.

4.5.1.3 Terrestrial Ecosystem Methodologies

The following sections present descriptions of two methodologies for performing quantitative risk characterization for terrestrial and aquatic ecosystems. Methodologies for characterizing risk to receptors in terrestrial and aquatic ecosystems are similar in some aspects, but are discussed separately because of differences in the data forming the basis for the final risk calculations.

4.5.13.1 Hazard Quotient (HQ) Method. The HQ method as applied to ecological risk is similar to that for calculating an HQ for human health risk characterization. The objective of a risk characterization for a specific receptor is to compare the estimated chemical intake of one chemical through one exposure route with the "threshold" concentration, that is, the level of intake that is recognized as unlikely to result in adverse ecological effects (i.e., the reference toxicity value, RTV). The comparison (quotient) of estimated intake and acceptable exposure level is called an HQ and is derived in the following manner:

$$HQ = \frac{\text{intake (mg/kg-bw/day)}}{\text{RVT (mg/kg-bw/day)}}$$

where the intake is the chronic or subchronic daily intake (expressed as a dose in mg/kg-bw/d) of the chemical (whichever is appropriate for the exposure being assessed) and the RTV is the corresponding threshold value (subchronic or chronic, oral) expressed as a dose. Short-term, subchronic, and chronic exposures should be assessed separately.

The HQ is used as a basis for deciding whether or not there is a negligible potential for ecological impacts. An HQ of 1 indicates that the estimated intake is the same as the RTV; an HQ of greater than 1 indicates the estimated intake is greater (i.e., the threshold has been exceeded): less than 1, it is less (i.e., the threshold has not been exceeded). The interpretation of the results of an HQ is outlined by Barnthouse et al. (1986) and others. In general, an HQ greater than 1 is interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate a lack of risk, but should be interpreted based on the severity of the reported effect and the magnitude of the HQ.

The HQ should not be viewed as a statistical value or risk: for example, an HQ of 0.01 does not indicate a 1-in-100 probability of the adverse effect occurring. Rather, it indicates that the intake is 100 times less than the RTV for the chemical. In addition, the Intake/RTV ratio does not infer a linear relationship, i.e., the hazards posed by exposure to the chemical do not increase linearly as the HQ increases linearly. This is so for several reasons, including the fact that RTVs are not precise descriptors of hazard (developed by using multiple uncertainty factors), and the severity of potential ecological effects varies with different chemicals (dose-response relationships differ).

To examine the potential for the occurrence of adverse ecological effects as a result of exposure to multiple chemicals through multiple exposure pathways, it is assumed that an adverse effect could occur if the sum of the HQs exceeds 1. In other words, even if exposure to each individual chemical is below its RTV (HQ ratio less than 1). if the sum of the ratios for multiple chemicals exceed unity, adverse ecological effects could occur. This is quantitatively derived in the following manner

$$HQ_i + HQ_i + HQ_i \ldots . + HQ_i = HI_j$$

where HQ_i is the HQ for an individual chemical and HI_j is the HI for a specific exposure pathway. To derive an overall HI, considering multiple co-occurring exposure pathways (and multiple chemicals), the following is performed:

$$HI_j + HI_j + HI_j \ldots . + HI_j = \text{Overall HI}$$

HIs should be expressed to one significant figure only, because of the uncertainties involved in deriving the RTVs. In addition, HIs should be reported in decimal form (e.g., 0.001, not 0.0012 or $1x10^{-3}$).

Deriving an overall I-II using an additive approach assumes the following:

- All chemicals will result in a similar adverse effect by the same mechanism of action (or same target organ).
- Each chemical exerts its effect independently (i.e., there is no synergism or antagonism).

Applying the assumption of additivity is a conservative approach that likely overestimates the actual potential ecological risk presented by the exposure. However, if the overall HI is greater than unity, consideration should be given to the known types of adverse ecological effects posed by exposure to the chemicals. If the assumption of additivity is not valid (i.e., if the chemicals most strongly contributing to the exceedance of the HI display very different types of adverse effects), the HI may be segregated according to toxicological endpoint. These segregated HIs may then be examined independently.

Segregation of HIs according to toxicological endpoints requires an expert understanding of toxicology and should be performed only by qualified individuals. Factors that need to be considered include the critical toxicological effect upon which the RTV is based, as well as other toxicological effects posed by the chemical at doses higher than the critical effect. Major categories of toxic effects include neurotoxicity, developmental toxicity, immunotoxicity, reproductive toxicity, and individual target organ effects (hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, dermal, and ocular) (EPA 1989f).

4.5.1.3.2 Probabilistic Methodologies. Probabilistic methodologies, which use distributions of effects levels and exposure estimates (as opposed to single exposure point estimates), may be used in the development of risk estimates. Risk is quantified by the degree of overlap between the two distributions -- the more the overlap, the greater the risk. To apply probabilistic methods such as these and to construct valid distributions, it is important that sufficient data amenable to statistical treatment are available[22] Collection of **such data, if not** available, may be more appropriately performed as a Tier II or higher effort. where actual field data are available.

Probabilistic methods can also be used for developing more appropriate exposure concentrations, where factors such as area use need to be considered. For mobile receptors such as fish, large herbivores, and predators, determination of dietary exposure concentrations should be "area" (i.e., feeding range) based rather than "point" (i.e., fixed location) based. Using probabilistic uncertainty analyses methods to create models that simulate random walks, probable exposure conditions for mobile receptors can be estimated under different time scenarios (daily, weekly, monthly, yearly).

A probabilistic uncertainty analysis, such as the Monte Carlo simulation, examines the range of potential exposures associated with the distribution of values for select or all input parameters of the risk algorithm. Probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values is generated that reflects the overall uncertainty of inputs to the calculation. The results are presented graphically as the cumulative exposure probability distribution curve. In this curve, the exposure associated with the 50th percentile of the exposure may be viewed as the "average" exposure and those exposures associated with the 90th or 99.9th percentile may be viewed as "high end" exposure.

---

[22] Although relatively simple to execute, probabilistic methodologies should be applied judiciously in ERAs (Burmaster and Anderson 1994). Using a probabilistic distribution for intake values and RTVs is only as appropriate as the quality of the input data. For example, using probabilistic distributions to account for a wide range of literature benchmark values that have not been reviewed for quality or applicability to site-specific conditions and receptors would not be appropriate.

Several computer-based proprietary simulation programs are available with which to conduct this simulation. Performance of a Monte Carlo simulation should only be performed by professionals with an understanding of the assumptions and limitations of using it, including such factors as identifying the appropriate number of runs and correlated input variables. An example of a Monte Carlo simulation is presented in Appendix E.

4.5.1.4 Aquatic Ecosystem Methods

The HQ and probabilistic quantitative methods can also be used for the estimation of risk to aquatic ecological receptors. The primary difference between aquatic and terrestrial receptors is that contaminant concentrations in surface water or sediments are used as input to the calculations instead of body-weight-based dose concentrations.

For calculation of an aquatic HQ, the comparison of a measured concentration in water or sediment with an appropriate aquatic RTV is as follows:

$$HQ = \frac{\text{measured concentration(mg/l)}}{\text{aquaticRTV(mg/l)}}$$

where the measured concentration may be the overall RME concentration, maximum concentration, or other appropriate measurement of exposure concentration and the aquatic RTV is the AWQC, sediment criteria (units would be mg/kg), or a species-specific RTV. As in the description of HQs for terrestrial receptors, an HQ greater than 1 is generally interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate lack of risk, but should be interpreted based on the severity of the potential reported effect and the magnitude of the calculated quotient.

HIs for multiple chemicals and multiple exposure pathways are the sums of individual HQs and pathway-specific HIs, respectively. It is only appropriate to sum the HQs for contaminants with the same toxic effect mechanisms (e.g., PAHs).

Probabilistic methods can also be used to estimate aquatic risk. Instead of using exposure concentrations in soils or forage, however, probability distributions of chemical concentrations in surface water or sediments are used. Comparisons of measured chemical concentrations can be made to probability distributions or point estimates of aquatic RTVs.

A number of other potential quantitative methods are available for use with aquatic receptors. In fact, nearly all of the ecological evaluation techniques previously listed are applicable to aquatic receptors.

4.5.2 Characterization of Uncertainty

In a Tier I ERA, uncertainty is usually presented as a qualitative discussion about the range of confidence in the risk estimation (i.e., low, medium, or high) accompanied by the factors that may contribute to an overestimation or underestimation of risk. Wherever possible, risk should be expressed in terms of magnitude, direction (over- or underestimation), and probability, using either a sensitivity analysis (examining the appropriateness of the risk estimation by maximizing one or more values) or a probabilistic analysis. By expressing risk in quantitative terms of probability, plus magnitude and direction, the risk manager is better enabled to make judgments on risks relative to other factors (such as costs), and not simply decide that uncertainty levels in the risk assessment must be reduced by further study.

452.1 Objectives

EPA has identified two requirements for full characterization of risk. First, the characterization must address qualitative and quantitative features of the assessment through a weight-of-evidence discussion. This was discussed in the preceding section. Second, it must identify any important uncertainties in the assessment. This section discusses methods of identifying and describing uncertainties in a risk assessment.

Full disclosure and clear articulation of risk uncertainties are guiding principles for this portion of the risk assessment (EPA 1992g, 1995a,d).

> "EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each EPA risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports and regulatory documents." (EPA 1992g).

Identification and discussion of uncertainty in an assessment is important for several reasons (EPA 1992g):

- Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk.
- Decisions must be made on expending resources to acquire additional information to reduce uncertainties.
- A clear and explicit statement of the implications and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.
- Uncertainty analysis gives the decision-maker a better understanding of the implications and limitations of the assessments.

The output from the uncertainty analysis is an evaluation of the impact of the uncertainties on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced (EPA 1992a).

4.5.2.2 Sources of Uncertainty in a Risk Assessment

Sources of uncertainty in a risk assessment exist in almost every component of the assessment. Uncertainty generally can arise from two main sources: variability and data gaps. Model error is an additional, potential main source of uncertainty that a risk assessor may encounter. Uncertainty from variability can enter a risk assessment through random or systematic error in measurements and inherent variability in the extent of exposure of receptors. Uncertainty from data gaps is most prominently seen in the screening or Tier I ERA, when numerous approximations are made regarding exposures, chemical fate and transport, intakes, and toxicity.

In the following sections, specific sources of uncertainty in a risk assessment are identified and discussed. Following this discussion, different approaches to conducting an uncertainty evaluation are presented.

The identification of the types and numbers of environmental samples, sampling procedures, and sample analysis all contain components that contribute to uncertainties in the risk assessment. Decisions regarding the scope of sampling and analysis are often made based on the ECSM developed at the planning stages of the investigation. While appropriate planning may minimize the uncertainty associated with these components, some uncertainty will always exist, because the "real" state of the site is unknown prior to sampling and, in fact, may not be fully elucidated even after sampling.

Some of the assumptions in this component that contribute to uncertainty in the assessment include:

- Media Sampled. Unless a decision has been made to sample all media, often a subset of media is selected for sampling and analysis. This selection is usually based upon the anticipated presence of a chemical in a medium from the site history and the chemical's chemical and physical properties and may not include consideration of potential transport through biological media. If all abiotic media in which a chemical is actually present have not been sampled, appropriate risks may not be described.
- Locations Sam&d. The type of sampling strategy selected may impact the uncertainty associated with the results. For example, purposive sampling (sampling at locations assumed to contain the chemicals) will likely result in a higher frequency of chemical detection and concentration than random sampling or systemized grid sampling. Therefore, use of the results may skew the assessment toward greater assumed exposures.
- Number of Samples. Fewer samples result in a higher degree of uncertainty in the results. This is demonstrated in the summary statistics, specifically the 95% UCL, in which the statistical descriptor ("t" or "II" value), and hence the 95% UCL, increases with a smaller number of samples. Planning for and success in obtaining a specific number of samples to reach a specific degree of statistical confidence can limit the degree of uncertainty.
- Sampling Process. The sampling process itself can contribute to uncertainties in the data from a number of factors, including sampling contamination (cross-contamination from other sample locations, introduction of chemicals used in the field); poorly conducted field procedures (poor filtering, incomplete cornpositing); inappropriate sample storage (head-space left in containers of volatile sample containers, inappropriate storage temperatures); sample loss or breakage: and

other factors. Some of these factors can be controlled by an adequate SAP; however, planning does not prevent the occurrence of sampling errors.

- Analytical Methodology. The analytical methodology can contribute to uncertainty in a number of ways, including the scope of the chemicals analyzed (if analysis of all important chemicals was not performed): the detection or quantitation limits applied (if not sufficient): and limitations in the analysis due to matrix effects, chemical interferences, poorly conducted analyses, or instrumentation problems. Some of these factors can be addressed in up-front planning (such as selection of the analytical method); others cannot (e.g., instrumentation problems).

- Stochasticity. Natural variability is a basic characteristic of ecological systems, as well as the factors which influence such systems (e.g., weather). Of all the contributions to uncertainty, stochasticity is the only one that can be acknowledged and described but not reduced (Suter in EPA 1992a).

Evaluation of the data to select COECs for the ERA may result in uncertainties. Application of selection criteria may inadvertently result in the inappropriate exclusion or inclusion of chemicals as COECs. Improper inclusion or exclusion of chemicals can result in an underestimation (if inappropriately removed) or overestimation (if inappropriately retained) of potential ecological risks. Uncertainties associated with the selection criteria include the following:

- Background Comparison. If background measurements are not truly representative of background conditions, chemicals may be inappropriately retained or removed from the list of COECs.

- Sample Contamination. Uncertainty in the assessment can occur if chemicals are not recognized as being present as a result of sampling or laboratory introduction and are included as COECs.

- Frequency of Detection. Use of a high detection frequency (say, over 5%) as a selection criterion may result in the inappropriate exclusion of chemicals as COECs.

- Toxicity/Concentration Screening. Removal of chemicals as COECs as a result of using a toxicity/concentration screen can result in uncertainty in the assessment, since some chemical contributors to the risk (even if not significant) have been removed

It is possible that the wildlife selected as key receptors in an ERA am not those receptors that have the greatest likelihood of being at risk or are sensitive to a particular chemical. Reptiles and amphibians are typically not addressed in ERAS, as exposure and toxicity data on which to base an assessment are generally lacking. Ecosystem and community level assessment endpoints such as adverse impacts to nutrient cycling, predator-prey relationships, community metabolism, and structural shifts are typically not addressed in ERAs. Uncertainty is associated with the professional judgment used in the selection of key receptors.

The ECSM is the product of the problem formulation phase, which in turn, provides the foundation for the effects characterization and risk estimation. If incorrect assumptions are made during development of the ECSM regarding the potential toxic effects or the ecosystems and receptors potentially impacted, then the final risk characterization may be seriously flawed.

Numerous assumptions regarding the amount of chemical intake by a receptor are commonly made as part of the exposure characterization. Such exposure estimates are associated with a number of uncertainties that relate to the inherent variability of the values for a given parameter (such as body weight) and to uncertainty concerning the representativeness of the assumptions and methods used. Uncertainties associated with chemical intake and exposure include:

- Potential Exposure Pathways. Potential exposure pathways are identified by examining the current and future land uses of the site and the fate and transport potential of the COECs. While current land use and potential exposure pathways are often easy to identify, potential future uses can only be inferred from information available at the current time. For many ERAs, potential future land use is assumed to be the same as current land use. This and any assumption regarding future land use, any potential future migration of contaminants offsite, and exposure pathways will add uncertainty to the assessment.

- Potentially Exposed Receptors. As discussed in the preceding bullet, identification of potentially exposed receptors is based upon information currently available. Assumed exposed receptors under future use scenarios can only be guessed at, and this adds uncertainty to the assessment.

- Exposure and Intake Factors. Point values (e.g., maximum or 95% UCL) for exposure estimates are commonly used in risk assessments rather than a distribution of exposure values that describe the distribution of exposures. These point values are usually conservative, and their use results in introduction of conservatism into the risk assessment that should be addressed. Use of average (i.e., central tendency), rather than upper-end exposure and intake factors may underestimate potential health risks, since only half the population is exposed to that degree or less; the other half is exposed to a greater degree. Using average values, therefore, also contributes to uncertainty that should be addressed in the assessment.

  Food and soil/sediment intake values for most wildlife are either unknown or highly variable and very site-specific. Food and sediment intake values for key receptors may be derived from allometric equations. Determining chemical concentrations in food may require the use of bioconcentration or bioaccumulation factors. Uncertainty exists in the use of such equations and factors.

- Exposure Point Concentrations. Exposure point concentrations may be derived either from measured site media chemical concentrations alone or in combination with fate and transport modeling. With regard to estimating exposure point concentrations from sampling data alone, use of 95% UCL and mean concentrations is associated with some degree of uncertainty. The 95% UCL concentration is used to limit the uncertainty of estimating the true mean concentration from the sample mean concentration. This value may overestimate the true mean concentration. Use of the sample mean concentration may under- or overestimate the true mean concentration.

  Application of fate and transport modeling adds an additional tier of potential uncertainty to exposure point estimates. Models cannot predict "true" exposure point concentrations at different times and places or in different media, but provide an estimate of the potential concentration under certain assumptions. Often, the assumptions used in the models are conservative to avoid underestimating potential concentrations. In addition, not all applicable processes are or can be considered (e.g., degradation, removal processes).

RTVs are developed from literature benchmark values by applying conservative assumptions, and are intended to protect sensitive species or populations. Use of non-site-specific, generic RTVs will usually result in overestimates of potential risk. Factors that contribute to uncertainty include:

- Use of UFs in the RTV. RTVs are primarily derived from laboratory animal toxicity studies performed at high doses to which UFs of 10 or more are applied.

- **Choice of Literature Benchmark Study to Derive an RTV. The inclusion or exclusion of studies in the derivation of an RTV is usually made by professional judgment; this affects the numerical RTV value.**

- The Assumption of the Most Sensitive Species. When deriving RTVs, the animal study showing an adverse effect at the lowest exposure or intake level is often the basis for deriving the RTV. EPA assumes that wildlife receptors are at least as sensitive as the most sensitive laboratory animal used (toxicological data on wildlife are still very limited). The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested than LD_{50} studies, while NOAELs from longer studies are the best (still imperfect) laboratory studies to use as predictors of field effects. The potential exists for wildlife species to be more or less sensitive than test species (some biota can adapt) and the toxicological benchmarks used Various uncertainty factors may be used to account for differences in taxonomic levels (i.e., species, genus, order, family) between the test species for the RTV and the key receptor(s) under consideration.

- Exposure Duration. Actual exposure durations for key receptors may or may not exceed the test duration periods on which the toxic literature benchmark value and resultant RTV are based. Because mobile receptors are likely to feed or

visit several locations, or avoid contaminated areas, their daily dose, if averaged over time, could be less than that used for evaluating risk. Unless exposure modifying factors are used, risk is likely to be overestimated.

Standardized algorithms to calculate chemical intakes and associated risks ate generally lacking for many wildlife receptors. There are numerous assumptions inherent in use of such equations that add uncertainty to the assessment. These include:

- Assumption of Additivity. Calculation of HIs assumes (at least as a first line approach) additivity of toxic effects. This assumption adds uncertainty to the assessment, and may result in an overestimate or underestimate of potential risks, depending on whether synergistic or antagonistic conditions apply.

- Omission of Certain Factors. Exposure modifying factors, such as absorption, bioavailability, soil matrix effects, area use, and exposure frequency should be considered. In cases where these processes are important, use of a standard algorithm without modification may result in an overestimation of potential chemical intakes.

4.5.2.3 Evaluation of Uncertainty

Various approaches can be applied to describe the uncertainties of the assessment, tanging from descriptive to quantitative. The method selected should be consistent with the level of complexity of the assessment. It may be appropriate to conduct an indepth quantitative evaluation of uncertainty for a detailed, complex assessment, but may not be appropriate or even needed for a screening level or simplistic assessment. In the section below, qualitative and quantitative approaches to expressing uncertainty are discussed.

4.5.2.3.1 Qualitative Evaluation. A qualitative evaluation of uncertainty is a descriptive discussion of the sources of uncertainty in an assessment, an estimation of the degree of uncertainty associated with each source (low, medium, high), and an estimate of the direction of uncertainty contributed by that source (under- or overestimation). A qualitative uncertainty assessment does not provide alternate risk values, but provides a framework in which to place the risk estimates generated in the assessment.

4.5.2.3.2 Quantitative Evaluation. A quantitative uncertainty assessment is any type of assessment in which the uncertainty is examined quantitatively, and can take several forms. A sensitivity analysis is one form in which specific parameters are modified individually and resultant alternate risk estimates are derived. Probabilistic approaches, which were described previously, are more complex forms of uncertainty analyses that simultaneously examine the combined uncertainty contributed by a number of parameters. An example of this approach, *Analysis of Extrapolation Error,* is presented in Barnthouse et al. (1986).

A sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. These results am used to identify the variables that have the greatest effect on exposure. This analysis is performed in three steps:

- Define the numerical range over which each parameter varies.

- Examine the relative impact each parameter value has on the risk and hazard estimates.

- Calculate the approximate ratio of maximum and minimum exposures obtained when range limits for a given parameter are applied to the risk algorithm. Exposure parameters should not, however, be combined in ways that are not reasonable: for example, combining maximum intake rates with minimum body weight.

4.5.3 Risk Description

Risk description has two primary elements. The first is the ecological risk summary, which summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimate through a discussion of the weight of evidence (EPA 1992a). The second element is interpretation of ecological significance, which describes the magnitude of the identified risks to the assessment endpoint and the accompanying uncertainty (EPA 1992a). A third element, discussion of the effect of additional data or analyses on uncertainty, should also be included.

4.5.3.1 Ecological Risk Summary

The ecological risk summary presents the results and uncertainties of the quantitative risk analysis. Weight-of-evidence discussions should be provided in the risk summary. The identification of data gaps and the need to conduct or not conduct additional analyses through another iteration (tier level) of the risk assessment process should be identified at this step.

4.5.3.1.1 Summary of Risk Estimation and Uncertainty. Every ERA should present the actual intake and risk calculations performed for the site in an appendix to the report. These calculations should show the chemical concentrations, the intake/exposure values, and the RTVs (including derivation) for each chemical assessed. A summary table should also be presented in the body of the risk assessment that provides a synopsis of the results of the quantitative assessment. This summary table should include the following factors:

- Receptor name
- All exposure pathways assessed for the receptor
- Risk and/or HI for each pathway
  - Expressed to one significant figure only
  - Short-term, subchronic, and chronic, as appropriate
  - Average and high end exposure
- Predominant chemical, i.e., the chemical contributing the greatest amount to the risk or hazard estimate
- Overall HI

A discussion should accompany the presentation of the quantitative risk estimates that interprets and qualifies the results, and highlights the important factors inherent in the values. Conclusions of the risk estimation should be described as some type of quantitative statement (e.g., there is a 20 percent chance of 50 percent mortality) (EPA 1992a). The uncertainties identified during the risk assessment are summarized either quantitatively or qualitatively, and the relative contribution of the various uncertainties to the risk estimates should be discussed wherever possible.

The summary of ecological risk should relate back to the originally selected assessment endpoints. The scale of the assessment endpoint is an important consideration in the overall interpretation of risk. Some degree of mortality, for example, can occur in a population without resultant significant adverse effects on the population.[23]

45.3.1.2 Weight of Evidence. In the characterization of ecological risk, the information collected concerning the identified hazards, the receptors, and the exposure characterization are integrated through a comprehensive ecotoxicological evaluation of source-receptor exposure pathways. After identifying sensitive receptors and habitats, complete exposure pathways, exposure points, and COEC exposure point concentrations, the potential for impacts is evaluated either quantitatively, qualitatively, or a combination of the two. Results from a variety of measurement techniques, such as toxicity tests and HIs, may be used in the weight-of-evidence characterization of potential and actual ecological risk.

If actual or potential adverse impacts are found, those impacts am further evaluated to determine to what extent they are site-related and to determine appropriate remediation goals. The ERA also includes conclusions regarding impacts from site chemicals, and a qualitative evaluation of limitations and uncertainties associated with those conclusions.

4.5.3.2 Interpretation of Ecological Significance

The interpretation of risk provides a critical link between the estimation of risks and the communication of assessment results. Ranges or levels that are considered acceptable by EPA are presented and discussed in the following sections.

4.5.3.2.1 Factors Influencing Ecological Significance. The relative significance of different effects may require further interpretation, especially when changes in several assessment or measurement endpoints are observed or

---

23 Although highly controversial, a 20% population reduction level is proposed by some as an acceptable threshold (Hull and Suter 1993). Selection of an appropriate and acceptable population reduction level ultimately depends on the site-specific population parameters and assessment endpoint for the receptor(s) of concern.

predicted (EPA 1992a). If the ERA is concerned with adverse impacts on a variety of receptors and different ecosystems, qualitative discussions should be presented as to the nature and magnitude of the potential adverse effects associated with each receptor and ecosystem.

The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance (EPA 1992a). Adverse effects to a resource that is small in scale relative to the site and/or area of contamination (e.g., a wetland or nesting grounds) may have a small spatial effect, but may represent a significant degradation of the resource because of its overall scarcity. Recovery potential is another factor influencing ecological significance that may need to be considered depending on the assessment endpoints (EPA 1992a).

4.5.3.2.2 Interpreting Site-Wide Ecological Significance. It is often the case at large Federal facilities that individual chemicals and ecological receptors are not isolated in the environment, and adverse effects are not necessarily related to a limited number of chemicals confined to the immediate location of discharge. Organizing the ERA to interpret the ecological significance of various chemicals to which a variety of ecological receptors are exposed at sometimes distant locations is challenging.

One means to organize and systematically consider the ecological significance of multiple receptors and multiple exposure pathways at large, complex sites is through the use of simplified ranking matrices (Figures 4-1 and 4-2) for important ecological receptors, based on the likelihood that they may be impacted by a specified pathway or numerous exposure pathways and COECs or COEC groups. For example, in the matrix shown in Figure 4-1, individual species (e.g., eagle or hawk) or groups of organisms with similar feeding strategies and habitat preferences (e.g., seed-eating birds, fish) arc listed in the left column. Across the top of the matrix are the chemical groups (e.g., heavy metals, pesticides and PCBs, munitions), exposure media (surface soils and surface water), and ingestion routes (primary or secondary). Differences in exposure between primary and secondary ingestion are principally due to differences in relative tendencies of the listed chemical groups to bioaccumulate and biomagnify through the food web. Each potentially completed exposure pathway is indicated by either an open (possible exposure) or a filled-in circle (potentially significant exposures).

This initial qualitative screening is done on a site-wide basis in order to refine the list of receptors that would be evaluated at smaller, separate locations (e.g., SWMUs or OUs). Completion of the matrix presented in Figure 4-2 provides identification of those key receptors likely to be at greatest risk, as well as those pathways which likely pose the greatest risk to various receptors at the facility. By identifying receptor(s) potentially at greatest risk and exposure pathways which potentially pose the greatest risk, the risk assessment process becomes more focused and manageable for interpretation. This same matrix (Figure 4-2) can also be used to rank COECs for each identified key receptor/exposure pathway combination.

Matrix ranking processes may be subjective, as in this example, or quantitative (depending on data availability) based on site characterization, ecotoxicological information, and EPA guidance. The ranking process may incorporate weighting factors to emphasize specific factors (e.g., area use, toxicity, exposure area, bioavailability, and biomagnification potential) which affect the ability of the chemicals considered to have a deleterious impact on the ecological receptors. Matrices can be updated or revised during the risk assessment process should additional data regarding the COECs, exposure pathways, or key receptors be identified. The additional data will enhance risk decisions for smaller locations within the facility (e.g., OUs/SWMUs) for which the risk assessment process has not been completed.

4.5.3.2.3 Discussion of Additional Data or Analyses. The third element, the risk description, serves as a conclusion and is an evaluation of the level of uncertainty and the potential for reducing the uncertainty by conducting additional analyses of the existing data, or collecting additional data and analyzing these data. The types of data needed to reduce the uncertainty (i.e., the data gaps) are examined, and an assessment of which tier to enter is made. Detailed descriptions of Tiers II, III, and IV are provided in Sections 5.0 through 7.0.

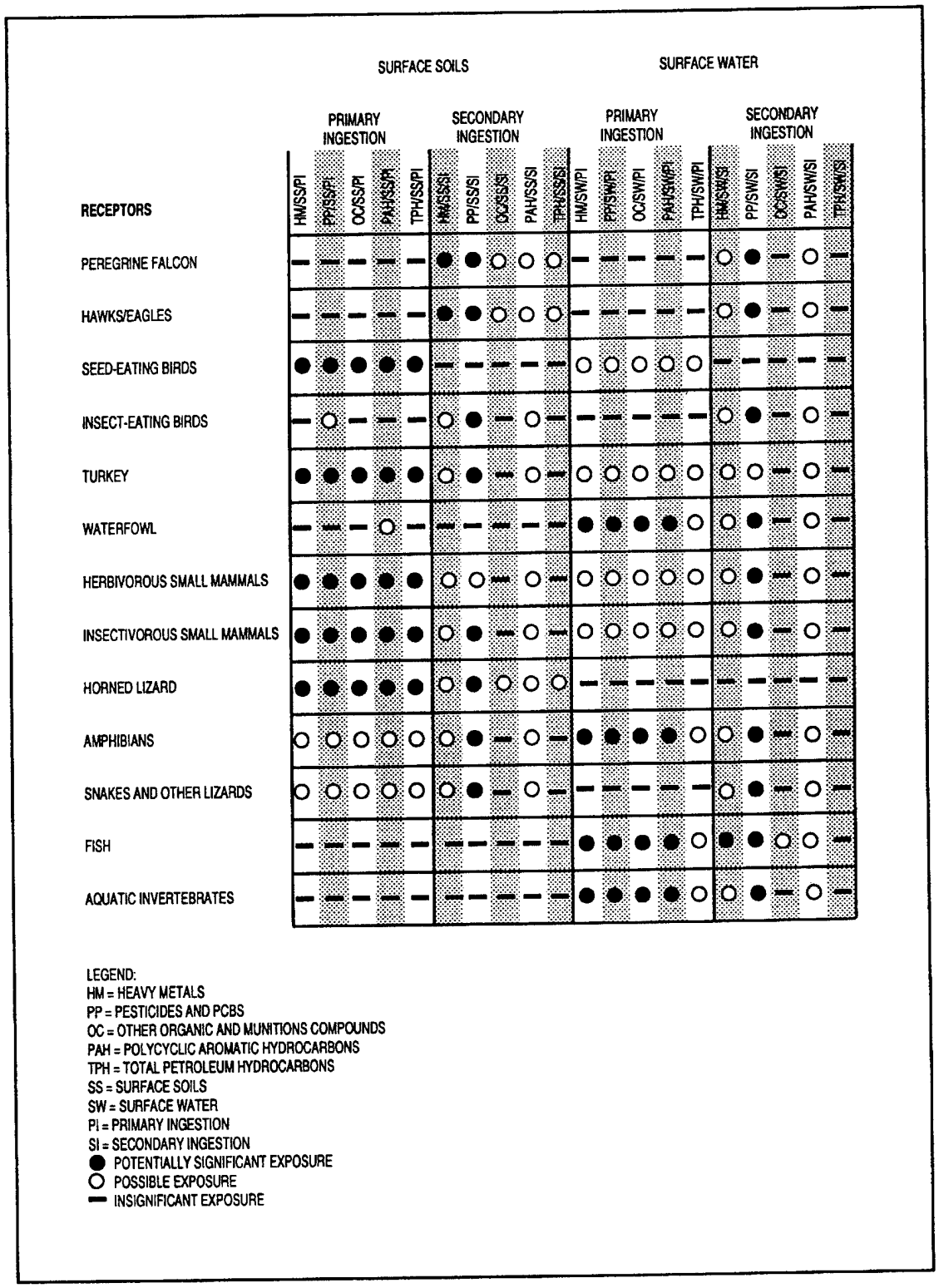


Figure 4-1. Site-wide exposure matrix

SOLID WASTE MANAGEMENT UNIT (SWMU)

RECEPTORS - CHEMICALS/INGESTION	1	2	9	10	12	13	14	15	16	17	18	19	20	21	22	23	24 & 35	25	26	27	28	30	31	32	36	37	38
PEREGRINE FALCON - HM/SI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
PEREGRINE FALCON - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–
HAWKS/EAGLES - HM/SI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
HAWKS/EAGLES - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–
SEED-EATING BIRDS - HM/PI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
SEED-EATING BIRDS - PP/PI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
SEED-EATING BIRDS - OC/PI	–	–	–	–	O	O	–	O	O	–	O	–	–	O	–	O	O	O	O	–	–	–	–	–	–	–	–
SEED-EATING BIRDS - PAH/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
SEED-EATING BIRDS - TPH/PI	O	O	O	O	–	–	O	–	–	O	–	O	–	–	O	–	●	–	O	–	–	–	–	–	–	–	–
INSECT-EATING BIRDS - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
TURKEY - HM/PI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
TURKEY - PP/PI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
TURKEY - OC/PI	–	–	–	–	O	O	–	O	O	–	O	–	–	O	–	O	O	O	O	–	–	–	–	–	–	–	–
TURKEY - PAH/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
TURKEY - TPH/PI	O	O	O	O	–	–	O	–	–	O	–	O	–	–	O	–	●	–	O	–	–	–	–	–	–	–	–
TURKEY - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HERBIVOROUS SMALL MAMMALS - HM/PI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
HERBIVOROUS SMALL MAMMALS - PP/PI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HERBIVOROUS SMALL MAMMALS - OC/PI	–	–	O	O	–	O	O	O	O	–	O	–	–	O	–	O	O	O	O	–	–	–	–	–	–	–	O
HERBIVOROUS SMALL MAMMALS - PAH/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HERBIVOROUS SMALL MAMMALS - TPH/PI	O	O	O	O	–	–	O	–	O	–	O	–	–	O	–	●	–	O	–	–	–	–	–	–	–	–	–
INSECTIVOROUS SMALL MAMMALS - HM/PI	–	O	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
INSECTIVOROUS SMALL MAMMALS - PP/PI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
INSECTIVOROUS SMALL MAMMALS - OC/PI	–	–	O	O	–	O	O	O	O	–	O	–	–	O	–	O	O	O	O	–	–	–	–	–	–	–	O
INSECTIVOROUS SMALL MAMMALS - PAH/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
INSECTIVOROUS SMALL MAMMALS - TPH/PI	O	O	O	O	–	–	–	–	–	–	O	–	–	O	–	●	–	O	–	–	–	–	–	–	–	–	–
INSECTIVOROUS SMALL MAMMALS - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–
HORNED LIZARD - HM/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	●	–	–	O
HORNED LIZARD - PP/PI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HORNED LIZARD - OC/PI	–	–	O	O	–	O	O	O	O	–	O	–	–	O	–	O	O	O	O	–	–	–	–	–	–	–	O
HORNED LIZARD - PAH/PI	–	–	O	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HORNED LIZARD - TPH/PI	O	O	O	O	–	–	O	–	O	–	O	–	–	O	–	●	–	O	–	–	–	–	–	–	–	–	–
HORNED LIZARD - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–
AMPHIBIANS - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–
SNAKES AND OTHER LIZARDS - PP/SI	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	O	–	–	–

LEGEND

HM = HEAVY METALS
PP = PESTICIDES AND PCBs
OC = OTHER ORGANIC AND MUNITIONS COMPOUNDS
PAH = POLYCYCLIC AROMATIC HYDROCARBONS
TPH = TOTAL PETROLEUM HYDROCARBONS

PI = PRIMARY INGESTION
SI = SECONDARY INGESTION
● POTENTIALLY SIGNIFICANT EXPOSURE
O POSSIBLE EXPOSURE
– INSIGNIFICANT EXPOSURE

Figure 4-2. SWMU specific exposure matrix

Chapter 5
Evaluating the Tier II Baseline Ecological Risk Assesment

5.1 Introduction

Proceeding to Tier II is recommended where there is a need to reduce uncertainty from previous investigative phases and to verify the Tier I findings. Proceeding to a Tier II, Tier III, or Tier IV ERA may also be necessary when field studies or bioassays are desired, when Tier I risk is not well-characterized, or when significant questions remain and remediation decisions cannot be adequately addressed (as part of the FS or RD). In Tier II, a shift is made to evaluating population and community level effects. as well as mixtures of chemicals and chronic effects using a biological effects-based approach. The overall objective in Tier II is to produce more accurate, quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to migration of chemicals from the contaminated site.

Tier II may include laboratory or field bioassays and/or more detailed, sophisticated computer models or probabilistic methods. Quantitative biological samples, as well as abiotic samples, as needed, may be collected to document exposure, to assess bioaccumulation potential, or to determine dose-response of the tested species or the selected receptors when exposed to site media. Limited field investigations may be conducted to determine presence of specific receptors or to estimate biodiversity. Tier II may include inexpensive, short-term toxicity tests or bioassays, standard rapid biological field assessment protocols, or focused tissue residue analyses of key receptors or their prey. As needed, semiquantitative sampling of the contaminated and reference sites may be conducted to describe the identity and populations of biota in both areas. If limited fate/transport modeling (e.g., one-dimensional analytical model) is used, site-specific input values for key parameters of the model may be needed.

The biological sampling methods employed in Tier II are simple, short-term, and inexpensive relative to Tiers III and IV. Tier II data, when integrated with data (primarily chemical) collected from the previous phases, should generally be adequate to provide information on the significance of potential or observed ecological effects, the need for remediation/removal actions, and the develop ment of preliminary cleanup goals based on ecological concerns and remedial action objectives.

For specific models and methods that may be employed in a Tier II or higher effort, recent publications from USAERDEC (1994), WERF (1994), and NOAA (1992) can be consulted. Additional resources for ERA sampling and modeling methodologies are provided in Appendix B, Information Sources.

The decision as to which tier to enter depends upon the nature of the site (large versus small site: simple versus complex ecosystems), type(s) of data required (single versus multiple measurement endpoints): and the methods to be employed (desk-top, field, or laboratory). Tie and cost limitations also determine level of effort and tier. Problem reformulation and the identification of data needs should follow guidance provided in the USACE (1995b) *Technical Project Planning* document. If the identified data needs are for short-term, focused, biological sampling and analysis methods, then Tier II activities are appro priate. It is possible, however, that a Tier III or, under unusual circumstances, a Tier IV program may be the more appropriate level of additional activities following Tier I.

In some situations, Tier II procedures such as bioassays may be initiated prior to completion of the Tier I ERA. For example, bioassays or measurements of biological integrity, rather than chemical analyses, may be preferred, or even required under some Federal regulations (40 CFR, Part 227.13, *Federal Regulations on Ocean Dumping of Dredged Sediments;* EPA 1991g) to determine whether a particular abiotic medium (sediment, soil, surface water) is toxic to biota or contains chemicals at concentrations of ecological concern. Exhibit 18 and Figure 5-1 describe such a case and present an example of how the tiered ERA approach may be followed in the assessment of sediment quality and characterization of risk in an aquatic ecosystem. Decisions as to which method to use depend on project objectives, data needs, desired certainty level, and the suitability of each method to meet these needs. A comparison of various methods for assessing sediment quality is shown in Table 5-1.

In addition to methods described in Risk Characterization (Section 4.5). the following tier descriptions mention only a few of the numerous field and laboratory methods that may be employed to better characterize risk or provide a basis for remediation decision-making. The need for measuring additional ecotoxicological endpoints in each tier should be carefully evaluated. When selecting ecotoxicological methodologies, the biological response under consideration and the proposed methodology should satisfy USACE (1995b) Technical Project Planning guidance, as well as consider the following more specific criteria:

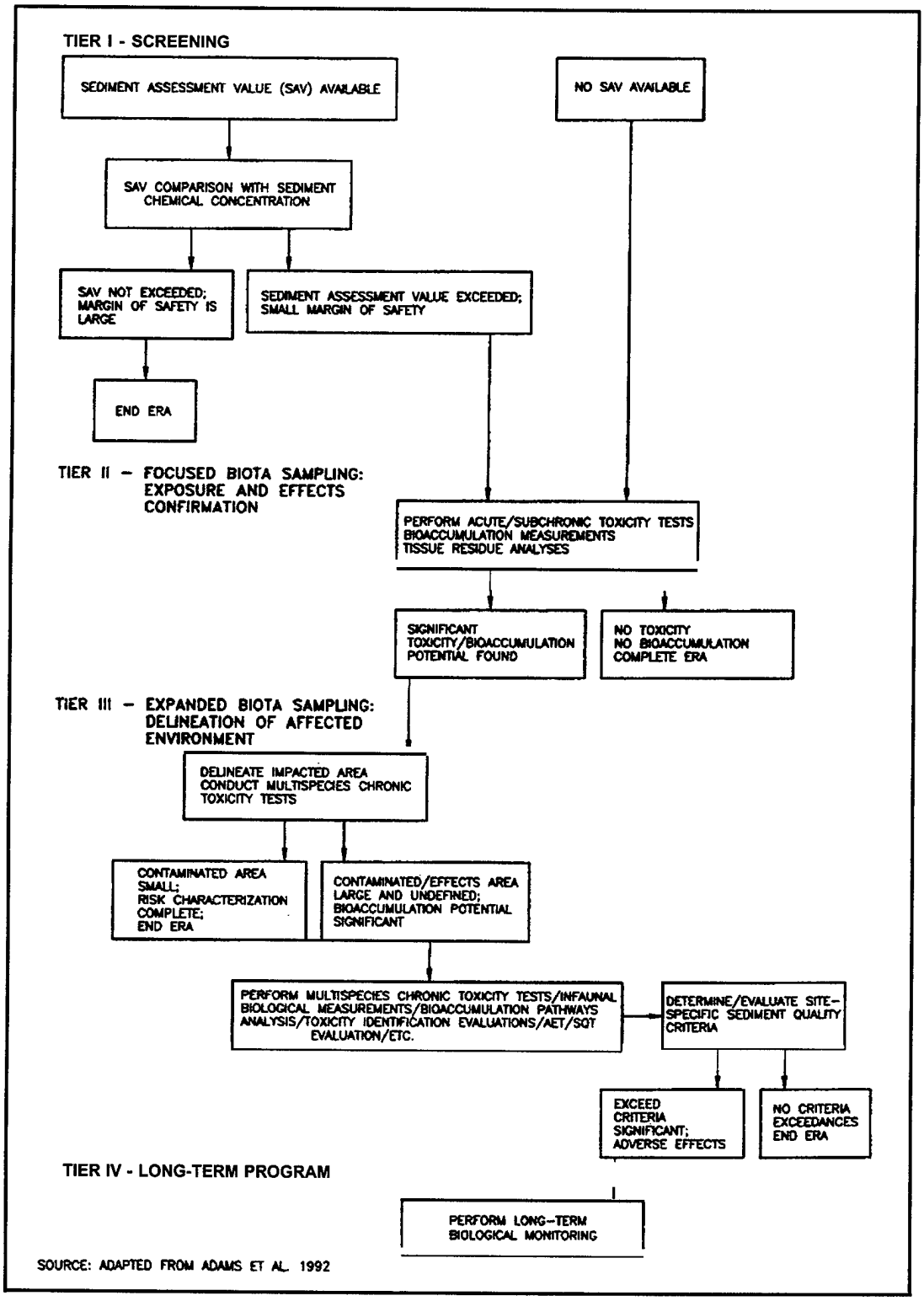


Figure 5-1. Interrelationship of tiers: Sediment quality assessment

Table 5-1
Comparison of Methods for Assessing Sediment Quality (See Exhibit 18)

Sediment Method	Chemical Specific	Site Specific	Integrates Multiple Chemicals	Field Validated	Relative Cost	Method Uncertainty[1]
Equilibrium Partitioning	Yes	No	No	Partially	Low	Moderate
Apparent Effect Threshold	Yes	Yes	Yes	Yes	High	Low/Moderate
Sediment Quality Triad	Yes	Yes	Yes	Yes	High	Low/Moderate
Bulk Sediment Toxicity	No	Yes	Yes	Yes	Low	Low
Interstitial Water Approach	Yes	Yes	Yes	Partially	Moderate	Moderate
Spiked Sediment Approach	Yes	Yes	No	Partially	Moderate	Moderate
Tissue Residue Approach	Yes	Yes	No	No	High[2]	Unknown
Freshwater Benthic Approach	No	Yes	Yes	Yes	High	Low
Marine Benthic Approach	No	Yes	Yes	Yes	High	Low
Ionic Chemicals	Yes	No	No	No	Low	Unknown
Metals	Yes	No	No	Partially	Low	Moderate/High

[1] The degree of uncertainty for each method is subjective and reflects the authors' opinion and experience. as well as previously reported evaluations
[2] The cost of this approach would be high if both sediments and tissue were analyzed.

Some: Adams, Kimberle. and Barnett 1992.

- The biological response is a well defined, easily identifiable, and documented response to the designated COECs (i.e., methodology and measurement endpoint are appropriate to the exposure pathway).
- Exposure to the COEC is known to cause the biological response in laboratory experiments or experiments with free-ranging organisms.
- Methodology is capable of demonstrating a measurable biological response distinguishable from other environmental factors such as weather or physical site disturbance.
- The biological response can be measured using a published standardized laboratory or field testing methodology.
- The biological response measurement is practical to perform and produces scientifically valid results (e.g., sample size is large enough to have useful statistical power and small Type II error).

The process for deciding which methods to use in each tier should follow Phase II project planning on DQOs, as well as general guidance provided in the following tier planning descriptions. Standardized protocol and detailed descriptions of some of the numerous ecotoxicological investigative methods available are provided in various agency (EPA, ASTM, FDA, USAERDEC, NOAA, WERF) publications (see Appendix B, Information Sources). Tables 5-2 and 5-3 provide an overview of the types of methods that are available and the types of information provided by such methods.

5.2 Problem Formulation

A listing and assessment of the ecological issues and data needs that remain following the Tier I ERA should be conducted The assessment and measurement endpoints used in the Tier I BRA should be reviewed to see if they

Table 5-2
Ecological Risk Assessment Approaches, Techniques, and Endpoints Used to Characterize Potential Risk

Characterization of Potential Risk				
Approaches	Techniques	Endpoints*	Information Provided	Information Not Provided
Comparison of Measured and/or Projected Contaminant Concentrations to Ecological Benchmark Levels	**Measured Concentrations** **Projected Concentrations (Quotient Method)**	**Mortality** **Reproduction** **Growth** **Community Structure** **AWQC** **NOELs/LOELs**	**Yes/No information as to whether impacts are likely:** **Impacts resulting from direct exposures as well as indirect exposure via food chains** **Ecologically based cleanup criteria for single contaminants**	**Quantitative measures of severity of impacts if benchmarks are exceeded** **Impacts to communities or ecosystems (unless benchmarks specifically account for these)**
Estimate of Exposure Potential (No Benchmark)	**Measured Concentrations** **Projected Concentrations** **Qualitative Evaluation**	**Mortality** **Reproduction** **Growth** **Community Structure**	**Types of ecosystems and receptors potentially exposed to contaminants** **Identification of potential exposure pathways**	**Likelihood or severity of impacts** **Areal extent and reversibility of impacts** **Uncertainty of the characterization.**
Estimate of Hazard Potential (Media Toxicity Tests)	**Laboratory Toxicity Tests** **In-Situ Toxicity Tests**	**Mortality** **Reproduction** **Growth** **Tissue Residue Level**	**Quantification of likelihood and severity of impacts to populations of test organisms** **Identification of hazards to site-specific populations** **Areal extent of impacts (if media tested at sufficient number of locations)** **Ecologically based cleanup criteria for mixtures of contaminants**	**Impacts to communities or the ecosystem:** **Interpretation of test results can be difficult (e.g., basis for the toxic response)**
Quantitative Risk Modeling	**Fault-Tree Analysis** **Probabilistic Pathway Analysis** **Multiple Attribute Ranking (Linear Models)**	**Reproduction Failure**	**Specific probabilistic prediction of the likelihood of specific impacts to individual organisms, populations, communities, or the ecosystem** **Severity and areal extent of impacts** **Quantification of ecological risks for risk management decisions**	Major disadvantage can be cost to implement

Source: EPA 1989k. Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs. EPA/600/8-89/043.

*** Definition of endpoint in this table is different from the *Framework* (EPA 1992a) definition of endpoint currently in use.**

are appropriate and applicable to anticipated remediation decisions. The additional biological/toxicological data requirements should be identified to help identify the appropriate tier and scope of additional investigations. Existing applicable data regarding potentially affected biological communities, environmental fate of COECs, bioconcentration and bioavailability of the COECs, toxicity data, and COEC concentrations in abiotic exposure media should be reviewed and data needs identified. Conclusions of the Tier I ERA that require a reduction in the associated uncertainty levels should be identified.

Once the additional data types that are needed are identified and the appropriate tier confirmed, problem formulation should commence. An initial step in problem formulation may be the development of working hypotheses. Hypothesis development is essential when statistical

Table 5-3
Ecological Risk Assessment Approaches, Techniques, and Endpoints Used to Characterize Actual Risk

Characterization of Actual Risk

Approaches	Techniques	Endpoints*	Information Provided	Information Not Provided
Evaluation of Biotic Community Structure	Quantitative Sampling	Diversity Indices	Identify large, major, and readily apparent impacts	Subtle impacts Impacts to populations Severity of impacts
	Qualitative Surveys Aerial Photography	Description of Community	Areal extent of impacts Identify small subtle impacts Potential exposure pathways and contaminant effects	Minor impacts Likelihood, severity or ecological significance of minor impacts
Evaluation of Individual Morphology or Physiology	Field Sampling Histopathology Necropsy Records of Mortality	Tissue Residue Levels Disease/ Abnormalities Reproduction	Direct evidence of injury to individuals Areal extent of major impacts to individuals	Impacts to populations, communities, or the ecosystem
	Detailed Field Studies	Tissue Residue Levels Disease/ Abnormalities Reproduction	Quantification of small, subtle impacts to individuals or populations	Impacts to communities or the ecosystem
Qualitative Surveys Aerial Photography				

Source: EPA 1989k. Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs. EPA/600/8-89/043.

*Definition of endpoint in this table is different from the *Framework* (EPA 1992a) definition of endpoint currently in use.

comparisons are anticipated (e.g., comparisons of onsite with offsite biotic populations).

Next, appropriate sampling and analysis methods should be identified and detailed Tier II work plans developed. The biological sampling methods employed should be simple, short-term, and inexpensive relative to Tiers III and IV. Because most of the sampling conducted within Tier II is short-term, seasonality of the species, population, or community to be sampled should be carefully considered, so that representative biotic samples can be collected. For example, if an assessment endpoint concerns adverse effects in nesting birds, then bird surveys should be conducted in the summer; if, however, the assessment endpoint concerns migratory bids, more appropriate seasons for surveys are spring and fall. Also, locations of biological sampling should be chosen in view of the previous sampling of exposure point media and any anticipated Tier II abiotic sampling and chemical analysis.

Tier II may include descriptive sampling and measurement of ecological attributes such as tissue residue levels or biological diversity in the contaminated area compared with a nearby reference area. Ecological attributes that can be adversely affected by contaminants are numerous (see Table 54). Selection of which attributes to measure should be well documented and based on USACE (1995b) Technical Project Planning guidance. Comparison of ecological attribute measurements made at the reference and contaminated sites can provide a qualitative measure of the ecological similarity between the two sites. Interpretation of the significance of differences in measurements between contaminated and reference sites is not always straightforward, especially where there are a large number of species present and the analyses become quite complex. The detection of differences between contaminated and reference communities does not necessarily indicate that contaminants are exerting biological effects.

Table 5-4
Ecological Atributes

Distribution
Sex-specific
Breeding-related
Age-specific
Food-supply related
Migration-staging related
Molting-related
Seasonal migration
Vertical migration

Population Characteristics
Population size
Uniqueness of population
Proportion of population likely to be affected
Location of recolonization populations
Population dispersion efficiency and mechanisms

Life History Characteristics
Fecundity
Number of offspring
Number of reproductions
Generation time
Mortality rate and pattern
Biochemistry and enzyme systems
Behavioral characteristics
  Dormancy
    Hibernation
    Estivation
  Physical movement
    Dispersal
    Migration
    Refuging
    Dispersion
  Selective behavior (e.g., feeding, habitat selection)

Habitat-Related Characteristics
Habitat specificity
Habitat availability
Extent of habitat
Potential for habitat destruction
  Direct vegetation destruction
  Factors affecting soil nutrients
  Factors affecting nutrient quality of vegetation
  Factors that interrupt energy flow or otherwise alter resource relationships

Community and Ecosystem Characteristics
Intra-specific competition stress
Inter-specific competition stress
Trophic relations
Species diversity and numbers/evenness
Food web diversity
Community structure
Primary/secondary production rates
Guild structure biomass
Nutrient transfer/cycling

Adaptation and Resistance
Induced detoxication mechanisms
Altered rates of uptake and/or excretion
Sequestering
Behavioral adaptation

Sensitivity Characteristics
Temperature tolerance
Depth tolerance
Salinity tolerance

Source: Conover et al. 1985, Stakhiv 1988.

When quantitative risk estimates are available and HI results indicate a significant potential for risk, conclusions from biological field studies and bioassays can be used as confirmatory weight-ofevidence to support risk conclusions and interpretation. Some additional abiotic sampling and analysis may also be needed so that the biotic data collected can he related to the chemical and physical habitat currently affecting the biota. The fate and transport of chemicals may be modeled in Tier II if needed to supplement the chemical analysis of physical media.

If there are indications that a NBDA action is being contemplated by the resource trustees for the site, it may be expedient to employ field collection efforts that satisfy both EEA Tier II data requirements and NRDA data collection requirements. For example, if baseline biotic data are to be collected from reference areas, they can be collected using methods that follow NRDA requirements for baseline determinations (43 CFR, Subtitle A, Part 11).

Following are brief descriptions of the focused field and laboratory studies appropriate within Tier II:

5.2.1 Field Studies

. Quantitative (semiquantitative) descriptive sampling in contaminated and reference areas to confirm the identity and quantity of potentially exposed biota or to measure other ecological attributes such as biological diversity (Noss 1990, Debinski and Brussard 1992) (Table 54). For example, data on vegetation community composition, structure, and diversity can be collected using semiquantitative methods such as

releve analysis and Braun-Blanquet rating methods (Mueller-Dombois and Ellenberg 1974).

- Tissue sampling of key receptor species or their dietary or prey items to document exposure. Tissue residue studies are used to provide site-specific estimates of exposure to higher trophic level organisms and to relate tissue residue levels to concentrations in abiotic environmental media. Knowledge of the physiology and biochemistry of the species to be sampled for residue analysis is important Species vary in their ability to metabolize various contaminants (e.g., fish can metabolize PAHs).

- One-time collection of exposure point media (e.g., surface water, sediment) for use in short-term (acute) laboratory bioassays.

- In situ acute bioassays, possibly using exposure point surface water and upstream water for dilution, to determine the LC_{50} contaminant concentration.

- One-time confutation surveys of Federal- or state-protected species to confirm their presence or document their potential presence (or presence of suitable habitat) and potential exposure to suspected COECs. This is in keeping with the NCP directive to "assess threats to sensitive habitats and critical habitats of species protected under the **ESA" [NCP 300.43(e0(2)(i)(G)].**

- If needed, one-time collection of exposure point abiotic media (e.g., soils, sediment, surface water) for additional chemical analysis to supplement existing chemical data.

- If needed, one-time collection of physical media from reference areas.

5.2.2 Laboratory Studies

- Laboratory analysis of biological samples (e.g., periphyton, benthic invertebrates, plants). as needed for taxonomy.

- Chemical analysis of collected tissue samples for COECs that are known or suspected of bioaccumulating or biomagnifying.

- Acute bioassays using onsite exposure media to **determine LC_{50}s or LD_{50}s.**

- Additional chemical analysis of exposure point media for specific species of COECs (e.g., chromium [+6] instead of total chromium) or selected COECs at detection levels lower than RTVs for the selected ecological receptors.

- If needed, chemical analysis of physical media collected from reference areas.

5.3 Data Collection and Analysis

Data collection from both field and laboratory studies and data analysis should be conducted in accordance with the Tier II work plan and USACE (1995b) Technical Project Planning guidance. The work plan should provide guidance from the USACE (1995b) Technical Project Planning document. At a minimum, the work plan should provide data collection objectives appropriate for Tier II, details of the proposed field studies methods, laboratory analytical methods with quantitation limits described, data quality review methodology, and plans for data presentation and integration with existing data, including data collected in Tier I.

5.4 Revision of the Tier I Era

Following the collection and compilation of biological/ toxicological data from field samples and laboratory analyses, the Tier I ERA should be revised to incorporate the information and results provided by the Tier II effort. This additional information can be used to provide further quantification of ecological risk assessment and to improve risk interpretation through additional weight-of-evidence. Overall, the additional information provided through Tier II investigations should reduce the level of uncertainty associated with the baseline ERA.

Chapter 6
Evaluating the Tier III Baseline Ecological Risk Assessment

6.1 Introduction

The Tier III ERA includes longer term field or laboratory studies (1 year or more), and employs more extensive (and more expensive) tests to resolve issues presented by larger sites having complex ecosystems and food webs. Depending on site conditions and complexity, elements of a Tier III ERA may be the most appropriate type of additional investigation following Tier I. The biological sampling conducted in Tier III may involve long-term (chronic) bioassays or tissue analysis of additional organisms or for additional analytes, and/or additional quantitative biological (i.e., population) sampling development. Data from quantitative surveys of populations and comparisons with reference location population characteristics may also be obtained in this tier.[1] Additional chemical analyses of abiotic exposure media also may be appropriate in order to ensure areal and temporal correlation with biological data, Additional ecosystem function or other field data may be collected, including nutrient loss (amount of undecomposed litter), biomarkers, histopathological examinations, or mesocosm studies (in situ biomonitoring). Site-specific input values for key parameters of the model are also needed, if more sophisticated fate and transport modeling is planned at this tier. Biological modeling may include single species modeling to evaluate exposure-response for a species co-located with multiple contaminants, to multiple-species pathway analysis to simulate bioconcentration/bioaccumulation within the community food web.

Results of the additional field and laboratory investigations fill the data gaps identified following completion of the previous tier (Tier II or I) and supplement the results from all studies conducted previously. The combined results are used to present revised risk estimates with less uncertainty than the preceding tiers, and provide a rationale for long-term monitoring (Tier IV) if needed,

[1] These characteristics include abundance, age structure, reproductive potential and fecundity proportion, productivity, standing crop or standing stock (total biomass), food web or trophic diversity, species diversity and dominance, presence of pollution tolerant/absence of pollution intolerant species, etc.

Tier III population studies may be required in the event that there is an apparent decline in a key receptor's population sire that is deemed important in the presence of a low HI, or no apparent effect on population sire in the presence of a high HI. Population studies are typically more long-term and complex, although simple, short-term population studies may be performed in Tier II. Population studies involve taking a census of the number of individuals in each life stage at several points over the course of one to several life cycles or seasons (USAF 1990). These studies can be expanded by including observations of the health or intoxication of individuals at different life stages for each time interval. The temporal aspects of the study design are likely to provide insight into age-related or life-stage-specific sensitivities of the organisms in question.

Tier III may also include sampling for model development or pattern description. Data may be collected to support single-species exposure models that employ Monte Carlo analysis techniques (Appendix E) or integrated fate, accumulation, and effects models, such as the pathways analysis model for estimating water and sediment criteria (Fordham and Reagan 1991). More intensive sampling to describe spatial patterns in biota and the extent of contaminant distribution in relation to these biological patterns may also be conducted in Tier III. Tier III investigations, if needed, are most likely conducted following a Tier II determination of the need for additional biotic data to support modeling efforts. It is possible, however, depending on site conditions, that a Tier III sampling and analysis effort may be the appropriate level of additional investigation following Tier I.

6.2 Problem Formulation

Following completion of the Tier I or Tier II ERA, adequacy of the results to support the FS/RD-RA should be examined again. If it is determined that expanded biological or toxicological investigations are needed to support remediation decisions, then guidance from the USACE (1995b) *Technical Project Planning* document should be followed. Similar to the problem definition stage of Tier II, previously collected Tier I and Tier II data should be reviewed and any data gaps identified.

Once data needs are identified, Tier III problem formulation should commence. The biological sampling methods employed are likely to be more extensive than those used in Tier II, but they should be complementary to those used in Tier II in order to have analogous data. Biological sampling locations should be the same as those in

Tier II unless they did not yield defensible biological data. If additional toxicological testing or tissue sampling is planned, organisms and methods used should complement those used in Tier II. Because of the elapsed time between tiers in the ERA, additional chemical samples may be needed to correlate with the additional biological and toxicological studies conducted in Tier III.

Following are brief descriptions of the field, modeling, and laboratory studies appropriate within Tier III:

6.2.1 Field Studies

- Quantitative biota (population/community) sampling extending over multiple seasons within one year to document seasonal variability of potentially exposed biota.
- Quantitative biota sampling in reference areas employing the same methodology used at the exposure points to provide sufficient data for statistical comparisons with the data collected at exposure points.
- Additional tissue sampling of the key receptor species or their diets or prey.
- Collection of exposure point media (e.g., surface water, sediment) for use in additional acute or chronic (long-term) laboratory bioassays.
- In situ acute or chronic bioassays to determine LC_{50}, LOAEL, or NOAEL contaminant concentrations.
- Additional surveys of Federal- or state-protected species suspected of being exposed to COECs.
- Additional sampling of abiotic exposure point media (e.g., soils, sediment, surface water) to supplement existing chemical data and correlate with the Tier III biological samples.
- Additional collection of abiotic media from reference areas for chemical analyses.

6.2.2 Modeling Studies

- Single-species modeling, which is a toxicity model based on a well-documented exposure-response relationship between a mixture of chemicals and a single species, can be run using Monte Carlo simulations to produce a cumulative distribution of projected ecological risk and can be run using various exposure scenarios representative of different remediation alternatives.
- Multiple-species pathways analysis modeling, which simulates contaminant trophic transfer potential through community food webs.

6.2.3 Laboratory Studies

- Laboratory analysis of biological community samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.
- Chemical analysis of collected tissue samples for COECs that are known or suspected of bioaccumulating or biomagnifying.
- Acute or chronic bioassays using onsite exposure media in order to determine LC_{50}s LOAELS, or NOAELs.
- Acute or chronic bioassays using doses of COECs suspected of presenting a risk in order to determine LD_{50}s, LQAEL, or NOAEL doses.
- Chemical analysis of exposure point abiotic media for the COECs, specific species of COECs, or selected COECs at detection levels lower than RTVs for the selected ecological receptors.
- Chemical analysis of physical media collected from reference areas.

6.3 Data Collection and Analysis

Data collection from both field and laboratory studios and data analysis should be conducted in accordance with the Tier III work plan and the USACE (1995b) *Technical Project Planning* document. As discussed for Tier II, the work plan should provide, at a minimum, data collection objectives appropriate for Tier III, details of the field studies methods, laboratory analytical methods with quantitation limits described, data quality review methodology, and plans for data presentation and integration with existing data, including data collected in Tiers I and II.

6.4 Revision of the Tier II Era

Following the collection and compilation of biological/toxicological data from the Tier III field samples and laboratory analyses, the Tier II ERA should be revised to

incorporate the information collected. In contrast to data from Tier II, this additional information is most appropriately used to better quantify the risk assessment. Overall, the additional information provided through Tier III investigations should further reduce the level of uncertainty associated with the ERA.

Chapter 7
Evaluating the Tier IV Baseline Ecological Risk Assessment

7.1 Introduction

Tier IV is reserved for the largest and most complex sites requiring multiple-year sampling or modeling programs and is only appropriate where data and an ERA with the highest degree of certainty are required for the FS/RD-RA. Complex sites are those with complex chemical interactions among numerous COECs and exposure matrices, widespread contamination or numerous contamination sources, and sites requiring the examination of potential risk reduction over time (e.g., Rocky Mountain Arsenal [EPA 1993f]). This tier includes biological studies of longer duration and greater expense (e.g., multiyear population and community level studies) or complex exposure modeling.

Tier IV investigations are expected to be warranted at very few sites. The Tier IV effort may require additional abiotic sampling and/or tissue residue sampling to establish correlation of cause-effect and or verification of a model.[1] To execute these models, a detailed understanding of the life history and population dynamics of species studied is required. Complex, mathematical ecosystem models which describe the mechanisms of action to address exposure processes and pathways and toxic effects are applied in this tier. Methods for linking laboratoryderived toxicity data to fish population models may be applied (Barnthouse, Suter, and Rosen 1990). Other models which address ecosystem functions (energy and nutrient cycling) may be developed.

7.2 Problem Formulation

Following completion of the Tier III ERA, adequacy of the results to support the FS/RD-RA should be examined again. Although unlikely, if it is determined that expanded biological investigations or complex modeling are needed to support multiple remedition decisions, then problem formulation for Tier IV should proceed. Similar to the problem formulation stages of Tiers II and III, previously collected data should be reviewed for adequacy and any data gaps identified.

Once the data needs are identified, Tier IV problem formulation should proceed. Biological community sampling methods employed in Tier IV may be more extensive than those used in Tier II and Tier III, but they are more apt to be the same as those used in Tier III. The sampling methods chosen for use in Tier IV would be used over a period of several years: however, timing of the sampling (e.g., monthly, seasonally) should be the same as in Tier III. Locations of biological sampling should be the same as those in Tier III. Because of the elapsed time between Tiers III and IV, additional chemical samples may be needed to support any biological studies and modeling conducted in Tier IV.

Following arc brief descriptions of the biological studies and modeling appropriate within Tier IV:

7.2.1 Field Studies

- Quantitative biota (population/community) sampling extending over multiple seasons and years to document long-term variability or trends of potentially exposed biota.
- Quantitative biota sampling in reference areas during selected seasons to provide sufficient data for statistical comparisons to the data collected at exposure points.
- Additional surveys of Federal- or state-protected species suspected of being exposed to COECs.
- If needed, collection of exposure point media for additional chemical analysis to support the biological sampling and modeling results.
- If needed, collection of abiotic media samples from reference areas.

7.2.2 Ecosystem Modeling Studies

- Complex, mathematical ecosystem models addressing such attributes as energy flow, material cycling, and food web assembly (Hull and Suter 1993).

[1] All these models are likely to require high costs and biological monitoring/field validation efforts involving multiyear and multiseasonal studies. These population and community models are often data intensive.

7.2.3 Laboratory Analysis

- Laboratory analysis of biological samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.
- If needed chemical analysis of exposure point media for the COECs or specific species of COECs.
- If needed, chemical analysis of reference area physical media for the COECs.

7.3 Data Collection and Analysis

Data from field and laboratory studies and modeling should be generated in accordance with the Tier IV work plan and USACE (1995b) Technical Project Planning document. As discussed above, the work plan should provide, at a minimum, a description of objectives appropriate for Tier IV details of the field and laboratory methods, including analytical quantitation Emits; full descriptions of the models to be used, including applicability of the model, assumptions, input data requirements, database compatibility, input/output formats, and output description; data quality review methodology; and field and modeling data presentation and integration with previously collected data.

7.4 Revision of the Tier III ERA

Following the collection and compilation of biological and modeling data from the Tier IV analyses, the Tier III ERA should be revised to incorporate the additional information collected. Overall, the additional information provided through Tier IV investigations should further reduce the level of uncertainty associated with the ERA. It is recommended that if multiyear biological sampling is included in Tier IV, the resulting data should be compiled, reviewed, and the ERA revised on an annual basis. By conducting annual data reviews and ERA updates, it may be determined that the Tier IV data collected to date are sufficient to provide risk-based answers to the remediation alternative questions, and further sampling is not necessary.

Chapter 8
Evaluating the Ecological Risk Assessment of Remedial Alternatives

8.1 Introduction

Various types of ERAs may be applied to conduct a screening evaluation of remedial alternatives or a more detailed analysis of a selected alternative. Generally, the Tier I baseline ERA will be sufficient in providing the risk inputs for selection of potential remedial alternatives or corrective measures (including the no-further-action alternative) or the need for procedural changes or engineering controls to minimize short-term risks 'or residual risks. Scoping of a higher tiered ERA may be necessary for sites requiring implementation of remedial action for a large areal extent and/or multiple years of remediation. and sites with complex ecosystems or trophic levels. Again, early project planning with involvement of expert ecological risk assessors, BTAG/ETAG persons, regulatory agencies, and stakeholders will be the key to avoid overscoping and to identifying the type of ERA most appropriate for specific site conditions.

The baseline ERA methodology presented in Chapters 4 through 7 has focused thus far upon the assessment methodology as appropriate for CERCLA RIs and RCRA RFIs. This methodology serves as the framework for all ERAs. As mentioned earlier, an ERA may also be performed for other aspects of site activities. One aspect discussed in this chapter is the performance of risk assessments to support activities undertaken during the FS or CMS. The two prime objectives of this type of ERA are: (1) the development of remediation goals to be applied to site cleanup, and (2) development of comparative risk assessments between different remedial options. The first type is sometimes performed as a component of the RI, but is distinguished in this chapter because of its use in the development of remedial options. The second type of ERA is not as commonly performed, but it can be useful in distinguishing between potential remedial options. Each type of BRA is discussed individually in the following sections.

8.2 Development of Remediation Levels

Remediation (remedial) levels, which are not synonymous with preliminary remediation goals or PRGs. are media-specific chemical concentrations that are associated with acceptable levels of chemical exposure for the site-specific ecological receptors. Remedial levels, also referred to as target cleanup levels, are considered along with other factors. such as ARARs. in identifying chemical concentrations to which impacted media may need to be remediated in order to achieve acceptable risk levels.

Remedial levels differ from PRGs in that site-specific factors am considered. PRGs are developed as a screening level tool prior to the performance of an RI or RFI. Conversely, remedial levels are developed from the site-specific baseline risk assessment that was developed during the RI or RFI. Remedial levels are just one element of the weight of evidence the risk assessment can provide to the risk manager to assist in remedial decision-making. Some regulatory agencies recommend including the development of remedial levels as part of the baseline risk assessment in order to assist the risk manager in the remediation decision-making process.

Remedial levels for aquatic systems may be derived by sorting and screening site-specific data on chemical concentration and co-occurring bioeffects in a manner analogous to the derivation of ER-Ls, TELs, and AETs (see Exhibits 7 and 18). Remedial levels may also be derived by performing the baseline risk assessment in reverse by rearranging the terms in the terrestrial or aquatic HQ equations:

$$HQ = \text{dose (terrestrial)} / RTV$$

where

$$DOSE = \frac{\text{chemical concentration (C) x ingestion rate (IR)}}{\text{body weight (BW)}}$$

for aquatic receptors

$$HQ = \text{concentration in water or sediment (aquatic)}/RTV.$$

The HQ (or HI) is set equal to an acceptable level (e.g., HQ = 1), the exposure route-specific intake factors developed during the baseline risk assessment are applied, and the chemical concentrations associated with the ingestion factors and HQs (or HI) am calculated. In the baseline risk assessment, hazards for terrestrial receptors are calculated by the following expression (equations are similar for aquatic receptors):

$$\textbf{Hazard quotient} = C \times (IF_1 + IF_2 + \ldots IF_n) \times 1/RTV$$

where

Hazard quotient = the hazard quotient associated with exposure of key receptors to the individual chemical

IF = the pathway-specific ingestion factors, each of which incorporates the intake rate, exposure frequency, exposure duration, body weight, and averaging time for the applicable exposure pathway (i.e., all of the risk equation except chemical concentration and reference toxicity value).

For example

$$IF_1 = \frac{\text{ingestion rate for water}}{\text{key receptor body weight}}$$

$$IF_2 = \frac{\text{ingestion rate for food (fish)} \times \text{BCF}}{\text{key receptor body weight}}$$

RTV = the reference toxicity value

C = the chemical concentration or remedial level associated with the HQ

To develop remedial levels, this equation is rearranged

$$C = \frac{\text{hazard quotient}}{[\ IF_1 + IF_2 + \ldots IF_n) \times 1/RTV]}$$

As this equation illustrates, remedial levels are chemical-specific. If more than one chemical is to be remediated at the site, the application of remedial levels developed by this approach can possibly result in residual risks exceeding the target hazard level.

Remedial levels should be based upon all key receptors and all significant exposure pathways assessed in the baseline risk assessment for that medium. However, since the pathways resulting in the highest degree of risk will most greatly influence the remedial level, exposure pathways that have minimal contribution to overall risks can be excluded from the remedial level development with little or no impact.

Exhibits 19 and 20 illustrate the development of remedial levels for a terrestrial receptor and for aquatic-based wildlife receptors, respectively.

8.3 Comparative Risk Assessment of Remedial Alternatives

As part of FS activities, different remedial alternatives are examined from a number of perspectives as part of the selection process. The NCP specifies nine selection criteria to be examined as part of remedial alternative evaluation: (1) protection of human health and the environment, (2) compliance with ARARs, (3) long-term effectiveness and permanence, (4) reduction of toxicity/mobility/volume through treatment, (5) short-term effectiveness, (6) implementability, (7) cost, (8) state acceptance, and (9) community acceptance. RCRA has similar criteria.

For a remedial alternative to be acceptable, it must be protective of the environment as well as human health. However, more than one alternative may meet this (and the remaining criteria). In these instances, an assessment of the long-term residual risks associated with both alternatives can be developed as a tool to assist in selecting an alternative. By comparing the degree to which an alternative reduces potential risks with respect to other factors such as cost, acceptability, and effectiveness, one alternative may be identified preferable. For example, Alternative A may reduce risks to an HI of well below 1, but cost $5 million to implement; Alternative B may reduce risks to an HI of slightly below 1, but cost only $1 million to implement. Since both risk (hazard) levels are acceptable in terms of the assessment endpoint, it may be preferable to select Alternative B because of its cost/benefit advantage.

In addition to cost, the reduction of risk offered by the alternative should be examined with respect to the risks estimated in the baseline assessment. If the risk reduction offered is not significant, or does not address the primary risks identified in the baseline assessment, these factors should be considered in the remedy evaluation.

The reduction of risk offered by the alternative should also be examined with respect to the nature of the assessment endpoint or the size of the population affected by the baseline risks or remedial alternative's reduction of risk. Although protection of all key receptors is the primary goal, a modest reduction of risk for large populations of key receptors may be preferable to a large reduction of risk for a small group of key receptors.

The potential risks to be addressed in a comparative risk assessment are those remaining after the implementation and completion-of the remedial alternatives (those potentially incurred during the implementation are discussed in Chapter 9). The calculational methodology for performing the comparative risk assessment is the same as for a baseline risk assessment. The potential exposure pathways and receptors should also be the same as the baseline risk assessment unless exposure pathways have been modified due to habitat removal, for example. The main factor that will change is the chemical concentration to which the key receptors may be exposed.

When developing an estimate of potential exposure point concentrations after remediation, careful consideration must be given to where remediation is to take place and where no action is anticipated. It is not uncommon for remedial actions to focus in some areas of a site, leaving others untouched. Therefore, estimating the potential exposure point concentration is not as simple as assuming exposure to the remedial level, but to a combination of attaining the remedial level in some locations, being below the remedial level at others, and perhaps exceeding the remedial level in some isolated areas where (for some other valid reason) remediation is not anticipated. The potential risks associated with different combinations of remedial alternatives can be addressed by examining each medium separately, and then combining the associated risks.

8.4 Other Applications of Ecological Risk Assessments

The same approach for development of remedial levels and comparative risk assessments can be applied to the support of RD/RA and the assessment of residual risk. Further discussion of the risks generated during remediation and the screening evaluation process for RD/RA alternatives is presented in Sections 9.2.3.4 through 9.2.3.6.

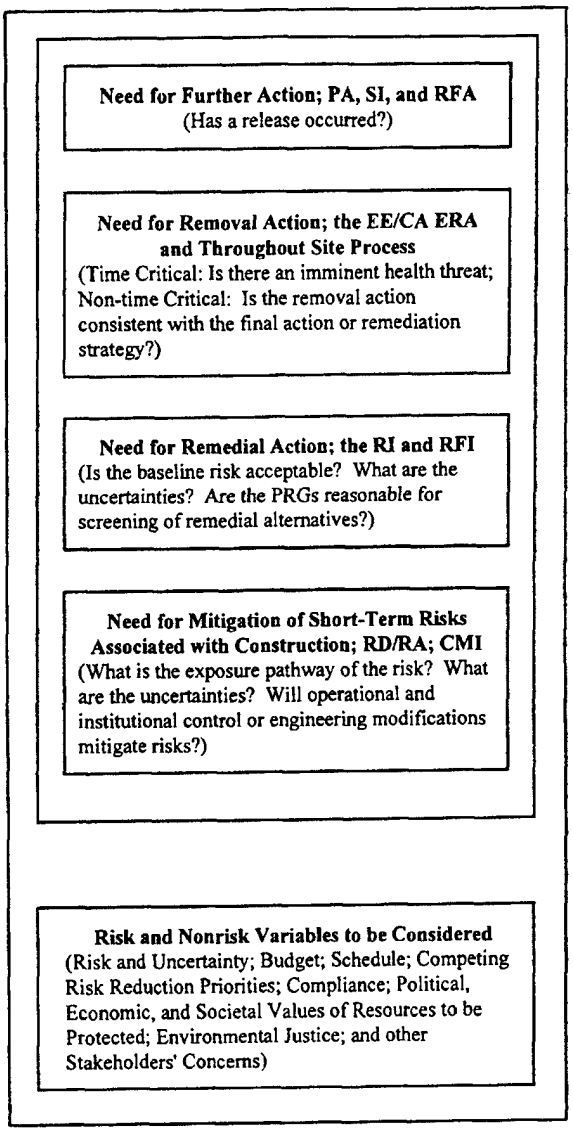
Chapter 9
Risk Management -- Information Needed for Decision-Making

9.1 Introduction

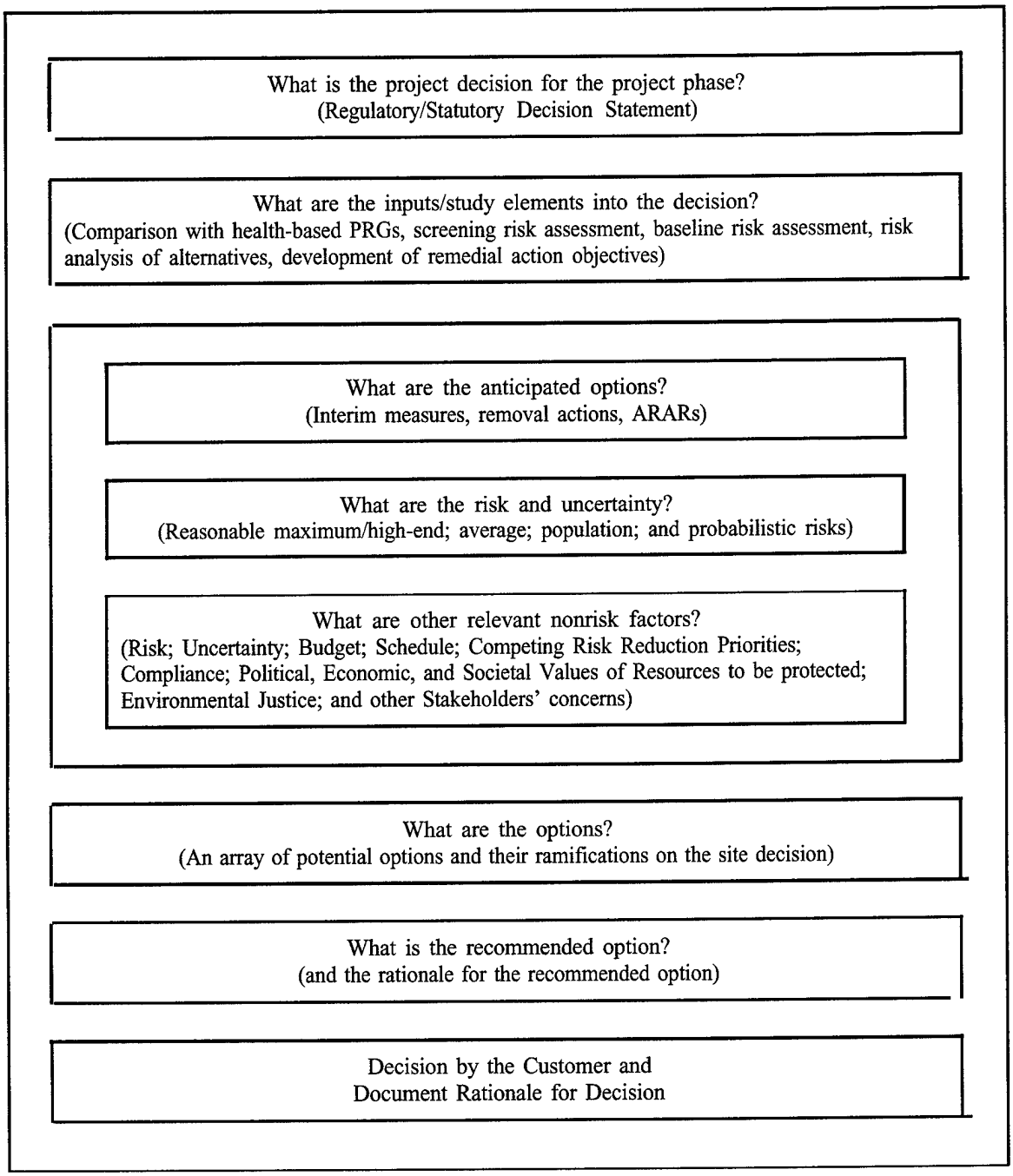
The National Academy of Sciences (NAS) defines risk management as "a process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NRC 1983). NAS has identified four key components for managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994). Risk characterization is considered the "bridge" or "interface" between risk assessment and risk management. EPA recommends that risk characterization should be clearly presented and separated from any risk management considerations. EPA (1995d) policy indicates that risk management options should be developed using risk input and should be based on consideration of all relevant factors, both scientific and nonscientific.

Consistent with NAS, USACE has developed the HTRW risk management decision-making (RMDM) process. This process identifies factors to consider when making decisions, developing and recommending options, and documenting of risk management decisions (Figures 9-1, 9-2). The process establishes a framework to manage risk on a site-specific basis. It emphasizes that risk management must consider the strengths, limitations, and uncertainties inherent in the risk assessment; the importance of public and other stakeholders' input; and other nonrisk factors. DoD has developed a similar concept to help prioritize installations according to environmental risks (see Section 1.3.1.1).

Risk and uncertainty are important factors to be considered in RMDM (EPA 1991d, 1995d). Other factors, including the customer's and stakeholders' concerns, cost, schedule, value of resources to be protected, political, and technical feasibility, are also to be considered before selecting the best option for a project decision. The consideration of risk is critical, since site actions are



Fibure 9-1. Inputs for risk management decision-making HTRW project decision diagram



Figures 9-2. HTRW risk management decision-making process flow diagram

driven by statutes and regulations which explicitly require the "protection of human health and the environment"[1]

Therefore, selecting the proper risk tool and collecting data to assess environmental risk are primary responsibilities of the PM and the risk assessor.

The HTRW risk management decision-making process can be represented by the following equation, with many variables contributing to the final decision:

$$RM = f(X_1, X_2, X_3, X_4 \ldots X_N)$$

where

RM = risk management decision

f = function of

X_i = input variables (e.g., risk and uncertainty)

In addition to risk and uncertainty, there are many nonrisk variables influencing the risk management decision. The major ones are cost, schedule, value of resources to be protected, competing risk reduction priorities among sites managed by the customer, compliance/regulatory, political, economic. and technical feasibility. A relatively sensitive political and/or economic factor to be considered is "Environmental Justice or Equity." This phrase relates to the government's initiatives to clean up sites located in "poor and disadvantaged" areas.

The risk assessment, in conjunction with other important "nonrisk" decision criteria, provides information on the need for remedial or early actions. Therefore, a clear understanding of the risk assessment results and their uncertainties is essential. Informed risk management decision-making will lead to protection of human health and the environment; cost saving: meeting the agreed schedule: political harmony; better management of resources; and other social and economic benefits. The HTRW RMDM process is consistent with recent initiatives by various EPA officials: Habicht (EPA 1992g). Denit (EPA 1993i). Browner (EPA 1995a). DoD (1994a) and various proposed legislations by the 104th Congress (e.g., Dole-Johnston Bill (S-343) and HR 1022) suggest that the need for risk reduction be based on "real world" or realistic risk assessment, cost benefit analysis, and prioritization of environmental issues. The HTRW RMDM paradigm (Figure 9-3) presents an overview of this process.

Prior to gathering data and performing the ERA, the PM defines the site decision for the project phase, the required study elements (types of ERA or risk tools to be used), and the potential uncertainties associated with the outputs of the study element. Based on risk information and other considerations, the customer can select from an array of recommended risk management options. Options can include gathering additional data, recommending no further action, interim measures, or removal and/or remedial actions. To facilitate RMDM, the USACE PM should anticipate potential risk management options early in the project planning phase. Examples of the use of risk assessment in various project phases include:

- PA/SI or RFA: A screening risk assessment, an environmental mapping, and an exposure pathways analysis may be performed to determine the need for further investigations.
- RI or RFI (prior to FS and CMS): The. baseline ERA determines the need for the remedial action.
- FS or CMS: Results of the ERA are used to develop preliminary remedial goals (i.e., chemical concentrations which pose acceptable hazard or ecological effects).
- FS or CMS: Qualitative or quantitative risk assessments to compare and evaluate potential ecological impacts from the remedial alternatives. A qualitative or simple quantitative risk assessment (like those used in the baseline ERAs) may be conducted to screen alternatives for their potential short-term and residual risks.
- RD (prior to conducting RA and CMI): Detailed risk analysis may be performed to determine if protective measures should be taken to minimize the impact to health and the environment during remediation. For example, a toxicity assessment

[1] Examples of these. requirements are 40 CFR 300.430(e)(1) of the NCP for deciding if remedial action is needed for a CERCLA site; RCRA Sections 3004(u), 3004(v), 3008(h), 7003 and/or 3013 for requiring corrective actions at hazardous waste treatment, storage, and disposal facilities to protect human health/environment; and the risk-based determination for no-further action (40 CFR 264.514) and selection of remedy (40 CFR 264.525) under the proposed Subpart S RCRA corrective action rules.

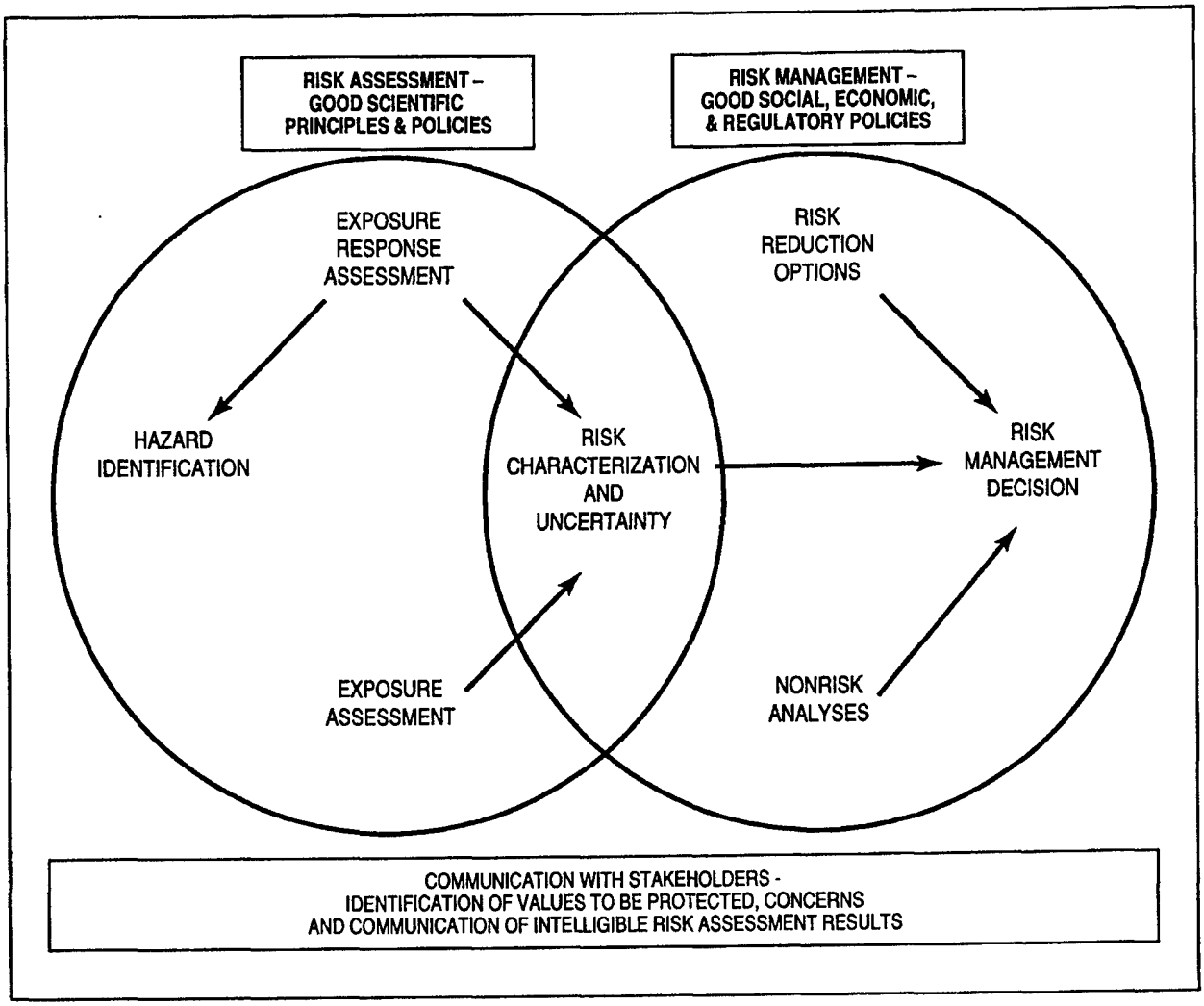


Figure 9-3. HTRW paradigm for risk management decision-making

may be conducted to evaluate the short-term acute, subchronic, and chronic ecotoxicities of potential releases from the remediation process. A hazard-response assessment should also be conducted to determine the design measures to reduce the impact of nonchemical stressors, e.g., habitat alteration and destruction, siltation, or other physical or chemical changes in the environment caused by construction of the remediation.

This chapter describes how the results of risk assessment procedures are to be used in risk management decision-making. The decisions include the need for further investigation, removal and remedial actions, selection of remedy, and provision of measures for designing removal or remedial actions that are protective of the environment (Figure 9-1). Information provided by the risk assessment is a key for selecting risk management options. Further, potential removal or remedial alternatives should be evaluated and compared according to their effectiveness to

reduce site risks, and any associated short-term risks posed by implementation of the alternatives.[2]

It is important to recognize that risk managers often make difficult decisions with considerable uncertainties in both risk and nonrisk information. Therefore. a focused and balanced risk approach is recommended that recognizes the reasonable limits of uncertainty for the protection of human health and the environment as the primary consideration, along with the considerations for nonrisk issues. The risk manager should clearly communicate the decision and the associated assumptions and document the basis for the decision. This chapter is organized to present the following information:

Section 9-2 describes how risk information can be used to support project decisions at various project phases (e.g., determining whether the project should proceed to the next phase or to site closeout). The section highlights key nonrisk considerations and emphasizes the importance of integrating the ERA results and uncertainties into an overall risk management decision.

Section 9-3 discusses the design considerations for implementing an overall site remediation strategy. Such a strategy considers issues such as offsite source areas, current and future land uses, compliance with chemical and site-specific ARARs (EPA 19891). and verification of cleanup.

9.2 Determining Requirements for Action

The fundamental requirement associated with any HTRW response action is the "protection of human health and the environment." This requirement focuses on the acceptability of site risks from the potential actions. section 300.430 (d) and (e) of the NCP (55 FR 8660, March 8, 1990) and the proposed RCRA Corrective Action Rule (55 FR 30798, July 27, 1990) require a baseline risk assessment or environmental evaluation to be performed to assess threats to the environment.

Risk management options are exercised in key phases of the HTRW project life cycle (see Table 9-1). Risk information required to support a decision is presented below:

9.2.1 PA/SI and RFA

The purpose of PA/SI under CERCLA and the RFA under RCRA is to identify if chemical releases have occurred, or if the site can be eliminated from further action. The PAs and RFAs are typically performed by the state, EPA, or the Federal agency, and are generally preliminary in nature. Under some circumstances Federal agencies may perform these activities with greater depth and vigor under Executive Order 12580. Unless good evidence exists that a site is contaminated, it is a crucial for the PM or the TM to methodically review each identified site. area of contamination, SWMU, and AOC, and decide if these units should be eliminated from the next project phase. In addition, it may be important to determine if an environmental threat or a substantial site risk potentially exists that would requite. an early response action (e.g., non-time critical removal actions, interim measures, or interim remedial action).

9.2.1.1 Actual or Potential Release/Exposure

Under the PA/SI or RFA phase, the risk management decision will be based on documented past spills and releases, the likelihood of such spills/releases, the presence of endangered or threatened species, sensitive environments or resources to be protected, and the existence of transport mechanisms that could bring the chemicals in contact with these receptors.

9.2.1.2 Potential Natural Resource Damage Assessment (NRDA) Action

Under CERCLA Sections 104(b)(2) and 107(f)(2)(C), the lead agency for cleanup (e.g., DoD, EPA) must notify appropriate Federal and state trustees of natural resources of any discharges or releases that may have injured natural resources under their jurisdiction. The PM is responsible for coordinating all response activities with the natural resource trustees. The PM should also consult with the USDOI (i.e., USFWS), DOE, or Department of

[2] This chapter does not address comparative analyses of other environmental risks, i.e., risks from radon gas, cigarette smoking, exposure to ultraviolet light due to stratospheric ozone depletion, ingestion of pesticide-contaminated food products, etc. These risks, although they may be significant in terms of the total risk posed to human receptors at a Superfund or RCRA site, are not related to HTRW site response actions and are considered background risks which are addressed by other environmental laws and policies. This chapter, however, does address the importance of risk assessment inputs in setting priorities for resource management with respect to environmental cleanup under RCRA and CERCLA. In making site risk management decisions, the PM should be familiar with the statutory language/limitations regarding the application of funds under DERA, BRAC, and other HTRW response actions.

Table 9-1
The Potential Use of Risk Assessment Concepts/Procedures as a Risk Management Tool

Project Phase	Objectives	Risk Management Options	Product/Deliverable
PA/SI, RFA	Should the site be eliminated from further evaluation? Identify sites with no release or insignificant release Site ranking/prioritization Need for removal action Need for RI or RFI	NO FURTHER ACTION (NFA); LIMITED SAMPLING/VER.; STAB, REMOVAL, RESP; LIMIT SCOPE OF RI/RFI; PHASED RI/RFI SAMPLING	Chemical fate and transport properties. Toxicity assessment (chemicals not expected to pose an ecological concern). Environmental mapping (sensitive receptors and food source identification). Exposure pathway analysis/food web and use of ECSM. Land use assessment.
RI, RFI	Does the site pose an ecological risk? Need for FS or CMS	NFA; MONITORING; INTERIM MEASURES/ INTERIM REMEDIAL ACTIONS; CONDUCT FS OR CMS	Baseline risk assessment. - Comparison with published criteria or benchmark toxicity values. - Toxicity-based ERA to assess stress-response relationship
FS, CMS	Preliminary Remediation Goals Select remedial alternatives	REMEDIAL ACTION OBJECTIVES; ONSITE/OFFSITE MANAGEMENT; NFA; MONITORING	Development of site-specific PRGs or benchmark toxtcity values. Assessment of short-term risks from remedial alternatives.
RD/RA, CMI	Protective control measures/remedy	EFFECTIVENESS AND DESIGN BASIS FOR CONTROLS TO REDUCE SHORT-TERM RISKS	Comparison with short-term acute risk levels. Exposure pathway analysis. Identification of impact areas, traffic patterns, and discharges.
Delisting/ site doseout	Residual risks & year review. permit review	NFA: MONITORING; RA OR CORRECTIVE MEASURES; ADDITIONAL FS AND RD	Land use/pathway analysis. Comparison with PRGs or RAOs Provide justifications for meeting cleanup objectives or technical impracticability.

Legend:

Technical Impracticability = technology not practical, e.g.. remediation of groundwater aquifer contaminated by dense non-aqueous phase liquids (DNAPL)

NFA = no further action
PRO = preliminary remediation goals
RAO = remedial action objective
RI/RFI = remedial investigation/RCRA facility investigation
SWMU = solid waste management unit
VER = verification

Commerce (DOC) where a discharge or release may adversely affect an endangered or threatened species or result in destruction or adverse modification of the habitat of such species. The trustees are responsible for assessing damages (i.e., monetary compensation) and presenting a "demand in writing for a sum certain" to the potentially responsible parties. Although the PA/SI or RFA is an early project phase and the potential for an NRDA action may not be known, the PM and the risk assessor should be cognizant of the potential when reviewing site history and background information. Any findings with potential implications for NRDA uncovered in this process should be provided to the customer and its legal counsel. This is recommended because the customer's goals for site close-out may be different upon further review of the potential for NRDA. By coordinating and working with Federal co-trustees, an overall remedial action (which might include restoration or mitigation) can be devised which will reduce an installation's NRDA liability.

9.2.1.3 Risk Screening and Prioritization of Units of Concern

Initial risk screening (Chapter 3) is an important tool for ranking or prioritizing units (OUs/SWMUs). This tool can result in substantial savings of resources, allowing the implementation of a more focused site investigation. The risk screening results are likely to provide significant inputs into the risk management decision-making for this project phase.[3]

[3] EPA's Deputy Administrator (1994) is concerned with the need for ensuring consistency while maintaining site-specific flexibility for making remedial decisions (from site screening through final risk management decisions) across programs. EPA stresses that priority setting is reiterative throughout the decision-making process because limited resources do not permit all contamination to be addressed at once or receive the same level of regulatory oversight. EPA suggests that remediation should be prioritized to limit serious risks to human health and the environment first, and then restore sites to current and reasonably expected future uses, whenever such restorations are practicable, attainable, and cost effective. EPA further suggests that in setting cleanup goals for individual sites, we must balance our desire to achieve permanent solutions and to preserve and restore media as a resource on the one hand, with growing recognition of the magnitude of the universe of contaminated media and the ability of some cleanup problems to interact with another.

It is not uncommon to have tens or hundreds of "sites" or SWMUs within a site or facility boundary. Risk managers at these facilities are faced with potentially complex investigations. Rather than taking a "piece meal" approach of investigation, the list of sites or SWMUs should be pared down if possible. The risk manager may negotiate with the agencies and enter in the IAG or FFA to permit the use of an approach that "addresses the worst sites first," and at the same time, group SWMUs within the same ecological receptor exposure units or geographical locations, as appropriate. This prioritization should result in the greatest environmental benefit with limited available resources. Site prioritization should include the following:

- Eliminate sites or SWMUs administratively by record review (including ascertaining if endangered or sensitive species/environment or valued resources are present on site), by interviews with current and former workers, and by ascertaining whether the unit of concern meets the definition of an "SWMU."
- Conduct a site reconnaissance and group sites or SWMUs with common exposure pathways or EUs, if appropriate.
- Rank the remaining sites or groups of sites qualitatively or quantitatively based on the ECSM or a screening risk analysis.

Generally, the above-listed tools will serve well if they are objectively and uniformly applied. The use of site prioritization:

- Provides justification for no further action (NFA) for low-priority sites.
- Allows better resource allocation for investigation of the remaining sites.
- Provides the opportunity to develop ECSMs to guide data collection (see Chapter 4).
- Helps identify potential boundaries where the ecological receptors of concern are to be protected.
- Identifies high-priority sites or SWMUs for non-time critical response actions.

DoD's (1994b) *Relative Risk Site Evaluation Primer* recommends evaluation based on three criteria: (1) contaminant hazard factor; (2) migration pathway factor; and (3) receptor factor (Figure 9-4). Information generated from the initial ecological risk screening (Chapter 3) can be used as a decision-malting basis using a similar site ranking process. Sites may be ranked high, medium, or low based on nonquantitative exposure pathway considerations such as the following:

(A) Significant Contaminant Levels

1. High Relative Risk Sites with complete pathways (contamination in the media is moving away from the source) or potentially complete pathways in combination with identified receptor or potential receptors.

2. Low Relative Risk: Sites with confined pathways (i.e., contaminants not likely to be released or transported) and limited potential for receptors to exist.

3. Medium Relative Risk: Sites with characteristics not indicated in the above.

(B) Moderate Contaminant Levels

1. High Relative Risk: Sites with complete pathways or potentially complete pathways in combination with identified receptor or sites with complete pathways in combination with potential receptors.

2. Low Relative Risk: Sites with confined pathways and any receptor types (i.e., identified, potential, or limited potential), or sites with potentially complete pathways in combination with limited potential for receptors to exist.

3. Medium Relative Risk; Sites with characteristics not indicated in (B)(l) and (B)(2) above.

(C) Minimum Contaminant Levels

1. High Relative Risk: Sites with complete pathways in combination with identified receptor.

2. Medium Relative Risk: Sites with potentially complete pathways in combination with identified receptor or sites with evident pathway in combination with potential receptors.

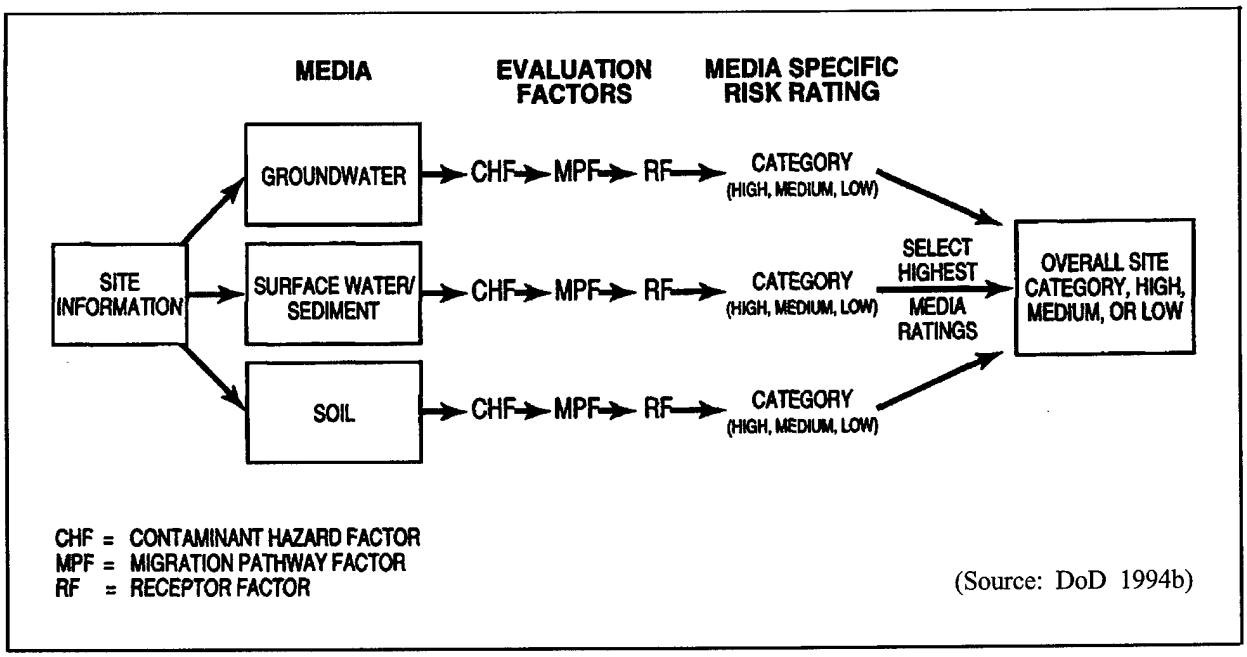


Figure 9-4. Flow diagram of relative risk site evaluation framework

3. Low Relative Risk: Sites with characteristics not indicated in (C)(2) above.

9.2.1.4 Risk Management Decisions and Options

Risk management decisions, risk information needs, risk assessment tools to satisfy the information needs, and risk management options are presented in this section. "Non-risk" factors to be considered in the decision-making are presented in Section 9.2.4.

Risk Management Decision

- Should a site be eliminated from further investigation in the RI or RFI project phase?

Risk Management Options/Rationale

- Further Evaluation Needed

Rationale: If a site cannot be justified for NFA. further evaluation (Expanded SI: Extent of Contamination Study: RI or RFI) will be needed.

- No Further Action (NFA)

Rationale:

- Environmental mapping, functional group characterization, database searches, or published lists from natural resources agencies indicate that endangered species are not present, and there are no sensitive environments or valued resources on and nearby the site.

  . No knowledge of documented releases or major spills/low likelihood of spills/procedures existed to promptly clean up all spills.

  . Transport mechanisms do not exist, e.g., presence of secondary containment.

  . The substances released are not expected to be present due to degradation and attenuation under the forces of nature.

- Spills or releases have been addressed by other regulatory programs (e.g., the Underground Storage Tank (UST) program or RCRA closure under Subpart G of 40 CFR 264 or 265).

  . The unit does not meet the definition of an "SWMU."

- The unit is part of another identified unit or site which will be addressed separately.

Although risk assessment is traditionally performed in the RI or RFI project phases of HTRW response actions, risk assessment can assist the risk managers in all project phases. Results of risk assessment activities are used to answer three key questions: I) whether or not there is a need to go forward with the next project phase, 2) whether or not early response actions (removal actions, interim measures, or interim remedial actions) should be taken to mitigate potential risks, and 3) effectiveness of the potential response action and the short-term risks associated with implementation of the removal actions.[4] Providing an understanding of the usefulness of risk assessment in the HTRW removal phase is the focus of this section.

Risk Management Decision

- Should early response action be undertaken to mitigate risk?

---

[4] Removal actions must be flexible and tailored to specific needs of each site and applicability, i.e., complexity and consistency should be used in evaluating whether non-time critical removal actions are appropriate. Examples of removal actions are: (1) sampling drums, storage tanks, lagoons, surface water, groundwater, and the surrounding soil and air; (2) installing security fences and providing other security measures; (3) removing and disposing of containers and contaminated debris; (4) excavating contaminated soil and debris, and restoring the site, e.g., stabilization and providing a temporary landfill cap; (5) pumping out contaminated liquids from overflowing lagoons: (9 collecting contaminants through drainage systems, e.g., French drains or skimming devices: (7) providing alternate water supplies: (8) installing decontamination devices, e.g., air strippers to remove VOCs in residential homes; (9) evacuating threatened individuals, and providing temporary shelter/relocation for these individuals (Superfund Emergency Response Actions, EPA 1990f). Items (3) through (5) could be used to reduce exposure to ecological receptors of concern.

Risk Management Options/Rationale

- No Early Response Action

  Rationale:

  - No imminent endangerment to ecological receptors of concern; lack of food sources to support or attract ecological species, lack of endangered species or sensitive environment/ valued resources, low likelihood of exposure by the receptors. (Uncertainty for the determination is related to thoroughness by the record search, visual observation, or purposive limited sampling.)

  - Transport mechanisms probably do not exist, e.g., presence of secondary containment.

  - Low concentration of site contaminants or the levels measured probably do not pose an acute hazard, and it is questionable whether the levels pose unacceptable chronic risk or hazard.

  - There is no anticipated risk of stress or physical hazards.

  - Site contaminants are not likely to be persistent or the contaminants are relatively immobile.

- Early Response Action

  Rationale:

  - There is no current impact, but if uncontrolled, the site could pose a substantial threat or endangerment to humans or the environment. (Examples ate: physical hazard, acute risk from direct contact of the unit or site, or effluents or contaminated media are continuously being discharged to the a sensitive environment, e.g., a spill that could impact salmon spawning, egg hatching, or survival of fry.)

  - The principal threat has reasonably been identified because of the evidence of adverse impacts. In this context, the COECs are known and the exposure pathways are judged to be complete, e.g., the exposure point or medium has been shown to contain the COECs.

  - Due to the slow rate of degradation, excretion, or depuration. the potential COECs may pose a threat to the food web via bioconcentration and biomagnification.

  - The boundary of contamination is reasonably well defined. so that removal action(s) can be readily implemented.

  - There is a potential risk to ecological receptors or valued resources and the removal or early response actions have been demonstrated to be highly effective in reducing exposure to ecological receptors of concern, although candidate removal actions may differ in terms of cost and magnitude of risk reduction achieved.

  - The early actions are consistent with the preferred final remedy anticipated by the customer, reducing risks to both human and ecological receptors.

  - The response action will be used to demonstrate cessation or cleanup of releases, resulting in substantial environmental gain which is the basis for early site closeout or further investigation.

  - If removal actions ate justified (e.g. addressing hot spots or high concentration plumes discharging to a receiving body of water with sensitive aquatic species, food chain, or valued resources), the removal actions will then be evaluated for their potential short-term risks and hazards, based on ECSM developed for the specific removal actions.

  - A high likelihood of releases and transport of site contaminants to the ecological receptors of concern, e.g., runoff from the site is expected to reach a receiving body of water containing endangered species or valued resources.

  - High concentration (acute hazard level) of site contaminant is found in the exposure medium.

  - Highly toxic chemicals or highly persistent and bioaccumulative chemicals found onsite which may be transported offsite.

- Documented unacceptable sediment, soils, surface water, or groundwater seep contamination in media that could be contacted by endangered species.

- Ecological impacts have been observed due to volume of the release and the habitat destruction of valued resources.

- A high risk of physical hazards or stress to the environment.

- The exposure pathway(s) for ecological species was the reason or one of the reasons for the basis for NPL listing or ongoing enforcement actions on spills or releases.

- Noncomplex site (no cost recovery issue, limited exposure pathways, small area sites, etc.)

Early response actions or removal actions, consistent with the final remedial action, may be taken to prevent, limit, or mitigate the impact of a release+ To encourage early site closeout or cleanup, EPA has encouraged early response actions at sites where such actions are justified. To the extent possible the selected removal actions must contribute to the efficient performance of long-term remedial actions. EPA's *RCRA Stabilization Strategy* (EPA 1992m) and *Superfund Accelerated Cleanup Model* (SACM) (EPA 1992n) emphasize controlling exposure and preventing further contaminant migration. While these concepts are intended to expedite site actions, risk assessment provides important information for justifying cleanup actions. The applicable risk assessment methods include:

- Environmental mapping/functional assessment.

- Exposure pathway analysis: development of ECSM.

- Identifying short-term (acute) benchmark toxicity values for screening site data.

- Qualitative evaluation of removal actions for their effectiveness to reduce exposure to ecological receptors.

- For complex sites (sites with multiple pathways, without ARARs, large geographic areas, and with a need for cost recovery), activities to support a baseline ERA may be appropriate.

In order to allow input for the removal actions, the risk assessment should be conducted in a timely manner. As an initial and highly conservative screening tool, comparison of worst-case exposure point concentrations can be compared with short-term (acute or subchronic) ecological benchmark values. Such risk evaluation should be qualitative, simple, and concise.

Early actions or accelerated cleanup can often be justified as long as the actions are consistent with the preferred site remedy. Since remedies am generally not selected until late in the FS or CMS, the customer's concept of site closeout and anticipated action is critical for deciding which types of early actions are appropriate. Based on experience gained in the Superfund program, EPA has identified certain site types where final remedies are anticipated to be the same (presumptive remedies). The current list of presumptive remedies includes:

- Municipal Landfill -- capping and groundwater monitoring.

- Wood Treatment Facility - soil and groundwater remediation.

- Groundwater contamination with VOCs - air stripping/capture wells.

- Soil contamination with VOCs - soil vapor extraction.

Additional presumptive remedies are being developed by EPA Region VII for PCB sites, manufactured gas plants, and grain fumigation silos. EPA is continuing to identify site types for which early actions are likely to result in substantial environmental benefits. However, it should be noted that certain sites are not conducive to early actions based on ecological concerns. Examples can include where: current and future. land use is highly industrial; there is a lack of food sources onsite or nearby the site for the ecological receptors of concern; there is low or generally low-level, widespread contamination; spilled or released substances are not bioavailable: contaminants have short halve-lives or are anticipated to degrade rapidly under natural conditions; there is a lack of viable environmental transport media (highly arid regions).

9.2.1.5 Qualitative Evaluation of Response Actions for Their Effectiveness to Reduce Risks

Removal of hot spots can provide substantial improvements in the site environment. In some cases, actions can reduce exposure to receptors drastically, and allow natural attenuation to further reduce exposure point concentration. If removal actions are needed, the risk manager should request two types of risk information. First, if there is more than one removal option, what is the comparative effectiveness of the options to reduce exposure and risks? Second, what is the risk or environmental impact associated with the. proposed removal action? To answer the first question, the HTRW risk assessor or risk manager provides information on bow the removal option can eliminate risk or reduce the level of exposure both onsite and offsite, if contaminant migration has occurred at offsite exposure. points. If substantial risk reduction can be obtained by all options, the risk manager should consider other factors, such as effectiveness, reliability, etc. To answer the second question, the project engineer estimates the destruction or treatment efficiency of the medium to be treated or disposed, and the type/quantity of wastes or contaminated debris to be generated for each potential option. This information is important if an action is likely to generate waste or damage sensitive environments in the course of the remediation.

It is important to communicate and obtain an early buy-in of the removal action from the local community. If the proposed removal actions are likely to pose unacceptable short-term risks to onsite or offsite ecological receptors, the removal action should either be discarded or monitoring/control measures be instituted. (As discussed later, the risk assesor and HTRW technical project planning team members provide options for making decisions when there are divergent interests between the protection of humans and the protection of ecological receptors of concern.) The risk assessor should work with other project team members to evaluate the potential for chemical releases or habitat destruction potentially associated with a remedial option. These evaluations should be qualitative and not extensive, and can be based on a consensus of professional judgment/opinion. These individuals should recommend alternatives or precautionary/protective measures to the risk manager to mitigate any potential risks.

9.2.2 RI/RFI

The primary objective, of RFI, RI, or other equivalent HTRW project phases is to determine if site contamination could pose potentially unacceptable human health or environmental risks. Determination of unacceptable risk, according to the NCP, is identified through a baseline risk assessment under "Reasonable Maximum Exposure." The RCRA corrective action process is similar to Superfund for determining the need for remediation, albeit initially, the TSDF owner/operator may simply compare a specific set of SWMU data with established AWOC or literature effect range levels. The proposed corrective action rule does not provide additional guidance on how action levels are to be developed for other media based on ecological concern. ERA generally considers performance of a Health and Environmental Assessment (HEA) to be functionally equivalent to the Superfund baseline risk assessment (human health and ERA) in the RI/FS while a few ERA regions have developed ERA guidelines for RCRA. The RCRA HEA should be conducted prior to or early in the CMS to determine the need for corrective measure implementation.

The ERA or HEA associated with the RI/RFI project phase can assist the risk management decision-making process in the following ways:

- The ERA presents the degree of site risk posed to ecological receptors and the associated uncertainties. Risks are generally assessed based on individual effects, although effects on populations and communities may be studied in the Tier IV assessment. Risks can be estimated for the entire site. OUs, AOCs, SWMUs, or CAMUS.

- Results of the ERA can be used to answer questions relating to the site decisions on: 1) whether sufficient information exists to confidently eliminate a site as posing no significant risk or there is a need to proceed to the next project phase; and 2) whether or not removal actions are still appropriate and should be implemented to mitigate potential ecological risks.

- If a site poses unacceptable acute or chronic hazard to ecological receptors, remediation will be needed for the significant exposure pathways. Pathways which do not pose an unacceptable risk may be eliminated from further concern. Algorithms developed in the ERA can be used in reverse to develop site-specific environmental-based preliminary remediation levels in the FS.

- If removal actions ate still appropriate and are to be implemented, the short-term impact of such actions should be evaluated.

Risk Management Decision

- Should remedial action or corrective measure be required based on the baseline ecological risk?

Risk Management Options/Rationale

. Further Evaluation Needed

Rationale: The ERA indicates unacceptable risk or the risk cannot be confidently established, and therefore the customer has weighed all options and determines the uncertainty associated with the ERA should be reduced. Further evaluation and/or data evaluation is needed to reduce uncertainty and determine ecological risk. Since risk assessment is an iterative process, data used to support the risk estimates should be critically reviewed by the PM. The review may lead to the need for additional data to more fully characterize potential risk. Alternatively, the manager may ask for a more detailed analysis of uncertainties so that the decision for remedial action can be made.

. Undertake Interim Response Action

Rationale: Action is based on finding of unacceptable risk to ecological receptors, after giving consideration to the uncertainties associated with the ERA. The selected interim remedial action or interim measure should be. part of or is consistent with the final anticipated remedy or corrective measure..

. No Further Action (NFA)

The rationale for no action based on the ERA could be any (or a combination) of the following:

Rationale:

- Documentation that endangered species or sensitive environments are not going to be impacted by the site due to the lack of complete exposure pathways, or the impact is judged to be insignificant or acceptable by the risk assessor and/or expert ecologist(s)/advisory panel such as BTAG/ ETAG.

- Lack of habitat or food sources to support the ecological receptors of concern and potential offsite migration of site-related COECs to any nearby habitats or food webs of concern is negligible, or site land use will remain industrial/ commercial based on stakeholder's inputs.

- The HQ is below unity or ten, as appropriate, based on uncertainty of the toxicity data (or the frequency of exceedance of this point of departure value is low). given the uncertainty inherent in the ERA involving multiple surrogate or indicator species (measurement endpoints).

- An existing ERA has been revised, reflecting that removal actions or interim measures taken have substantially reduced the exposure to the level that the estimated risks am acceptable.

- The potential environmental risk or injuries associated with any and all remediation is grater than the baseline risk (i.e., further efforts should be expended to find a suitable remedial action or viable alternatives, such as offsite mitigation, restoration, or compensation).

- With source control in place, given natural attenuation of the COECs (based on fate and transport properties), risk is expected to be short-term, and remediation is judged to be cost-prohibitive.

- There could be marginal risks: however, considering uncertainties, the potential incremental gain does not justify the action.

- No practical remedial action objectives or target cleanup levels can be established to sufficiently document risk or such levels would be highly uncertain and the environmental gain cannot be readily measured.

- Potential remedy will cause substantial economic or scenic damage and is not consistent with the public and stakeholders' goals and objectives.

- Interim remedial action or interim measures have removed the migration/transport mechanisms to impact ecological receptors.

- Site contaminants are not likely to ever pose unacceptable risk as they am not persistent or the contaminants are relatively immobile and not bioavailable.

. Remediation/Removal Action Required.

The requirement for removal action taken at the RI/FS or RFI/CMS project phase is the same as that described under Section 9.2.1.4 above. Upon

completion of RI/FS (and before signing of the Superfund Records of Decision or the completion of RCRA Part B permit modification), a decision will be made whether remedial action or RCRA corrective measure implementation should be. required. If there are site ARARs, such as state water quality standards, remediation will be required unless an ARAR waiver is successfully completed. From the risk assessment standpoint, if the baseline ERA is valid and the uncertainty deemed to be acceptable, requirements for remediation for part of or the entire site will be based on the following considerations:

- Endangered species or sensitive environments/ valued resources such as viable wetlands or wildlife refuge could be impacted by the site, and the estimated risk is judged to be significant or biologically relevant.

- Viable habitat and sufficient food sources are available to sustain the ecological receptors of concern.

- The COECs are persistent or bioaccumulative and will potentially impact ecological receptors of concern.

- The site poses an unacceptable risk.

- The environmental risk associated with the remedial action or the corrective measure implementation is acceptable.

- Short-term impacts from remediation, although potentially severe, are not permanent and outweigh the alternative of long-term, chronic exposure.

- COECs are persistent and expected to pose a long-term threat to the ecological receptors of concern.

- The remedial action objective (RAO) or target cleanup level (TCL) is based on a reliable or adequately characterized exposureresponse relationship and is practical for use to verify cleanup and the environmental gain is measurable.

- There is a low potential for recovery without removal or remedial actions.

- Remediation is consistent with the stakeholders' goals and objectives.

9.2.2.1 Risk Characterization/Uncertainty Information for RMDM

The sources of uncertainties in a Tier I baseline ERA were presented in Chapter 4. The objective of the risk characterization and uncertainty analysis is to make the ERA transparent to the risk managers and the stakeholders so that informed risk management decisions can be made. Given proper early project planning, it is expected that uncertainties will be acceptable to the risk managers and other stakeholders, including the BTAG members and other independent expert ecologists. The risk manager can balance his or her selection of options with the findings of the risk assessment and the degree of uncertainty in mind.

From the risk manager's perspective, the baseline ERA should adequately present risk estimates in an objective and unbiased manner. The risk manager or PM understands that although the risk assessment is a scientific tool, the results cannot be easily used to determine specifications. Moreover, it is a tool for risk management decision-making, and is rarely a tool for the prediction of actual occurrence of environmental effects. Therefore, as long as the uncertainties are presented and understood by the customer and other decision-makers, the results can be accepted or rejected for use in site decisions.

When making site decisions, the risk manager or PM can substantially benefit from consultation with responsible technical experts (risk assessors, expert ecologist[s]/ advisory panel [BTAG/ETAG]). It is the responsibility of these experts to document and present uncertainties so the risk manager or PM makes an informed decision. In the final baseline ERA, the risk assessment summary presents risks and the associated uncertainty information in a weight-of-evidence discussion which focuses on strengths and weaknesses of the risk estimates, providing information to assist in determining the overall objectives and decisions to be made in this project phase.

In order to make informed risk management decisions, the risk manager should have a clear understanding of the following:

- What are the receptors or resources to be protected?

- Does the ecological risk involve individual organisms, communities, populations, or different trophic levels?
- What is the aggregate hazard index (HI)?
- How do effects or ecosystem characteristics between the site and the reference locations compare.?
- What is the likelihood of recovery based on consideration of the contaminants' fate and transport properties, the substrate or media characteristics, natural attenuation, and lessons learned from similar sites?
- How do hazards under RME and average (typical) exposure compare? What are the "or&r of magnitude" differences?
- What is the key and overall uncertainty of the baseline ERA in terms of chemical data, COEC selection, exposure assessment and modeling, toxicity information, and characterization method? Is uncertainty quantifiable to the extent that the TCLs could be substantially altered?
- If the risk estimates are unacceptable, will quantitative analysis of uncertainty be able to demonstrate that the risk estimate is based on overly conservative assumptions, i.e., in the theoretical upperbound range?
- What are the COBC(s) and exposure pathways that constitute the principal threat?
- How are the exposure units defined in the baseline ERA?
- Are there any "hot spots" which would require further characterization. or removal action?
- Are there any acute hazards or risks which will require emergency response or removal action? Is there a risk of further spills, releases, or physical hazards that could further degrade the environment or adversely impact the ecological receptors of concern?
- If removal or early response actions are desirable, how effective are the proposed removal actions to reduce site risk?
- Which are the anticipated or preferred options for actions?

9.2.3 FS/CMS and RD/RA

The FS or CMS is triggered when the baseline risk is unacceptable and remediation is needed to mitigate risks and prevent further contaminant migration, In some instances, the FS or CMS could be driven by a legal requirement to meet ARARs, although ARARs are not necessarily risk-based The FS or CMS evaluates potential remedial alternatives according to established criteria in order to identify the appropriate remedial alternative(s). The FS or CMS can be performed for the entire site or any portion of the site that poses unacceptable risks. The results of the FS/CMS include recommendations for the risk managers or site decision-makers, including an array of remedies for selection, RAOs, or TCLs for verification of cleanup.' The selected remedies/TCLs or revisions thereof will be entered into the ROD or the Part B permit.

Risk Management Decision

- What are the Remedial Action Objectives (ROAs)?

Risk Management Options/Rationale

The risk management decision for selection of final remedies depends substantially on the RAOs. Uses of RAOs are summarized below:

- Developed or agreed upon by the agencies prior to the FS or signing of the ROD (or modification of the RCRA permit), RAOs are used to evaluate the feasibility of candidate remediation technology in the FS;
- Initial estimation and costing of remediation (e.g., excavation and stabilization);
- Delineation of cutlines for remediation:

[5] For the purpose of protecting the environment, the TCLs, sometimes known as RAOs, may be the same as the environmental-based preliminary remediation levels, or they may be different. TCLs or RAOs are negotiated levels for verification of cleanup and take into consideration performance of the proposed cleanup technology, practical quantitation limits, and uncertainties associated with the preliminary remediation levels to protect ecological resources of concern.

- For use in negotiation or final determination of specific areas, SWMUs, or site-wide cleanup goals, by considering uncertainties, technology, and cost.

Before embarking on an FS, RAOs should be developed using site-specific risk information consistent with site conditions. Factors to be cons&red when RAOs are used as the basis for designing and implementing remediation are presented below:

9.2.3.1 Remedial Action Objectives Must be Based on ECSM

The ECSM provides the framework for the baseline ERA and identifies the specific pathways of concern. RAOs must be able to address these pathways and the associated risks. A refined ECSM, based on the results of the ERA, is paramount to the establishment of focused RAOs. The RAOs are based on preliminary remediation levels developed as the project strategy goals in Phase I of the HTRW project planning under RI/FS or RFI/CMS.

9.2.3.2 Remediation Goals Must be Protective and Practical

Remediation goals are performance and numerical objectives developed in the FS/CMS to ensure that the remedial alternative will contribute to site remediation, restoration, and closeout/delisting. As such, they must be protective and workable. To ensure protectiveness, risk-based preliminary remediation goals should be first derived using the screening or baseline ERA procedures in reverse (see procedures described in Chapter 8). The uncertainty associated with development of the remediation goals should be discussed and quantified Preliminary remediation levels can be derived early in the site investigation process or at the end of the RI, when it is determined that remediation may be needed because of unacceptable risks. Site decision-makers carefully consider technology, practical quantitation limits, ARARs or to-be-considered criteria, reference location concentrations, acceptable hazards, field or laboratory analytical uncertainties, etc., before setting the RAOs.[6]

[6] Certain sites may be. contaminated with natural or anthropogenic substances which pose matrix interferences and cause high sample detection limits, i.e., the practical quantitation limits (PQLS) may be higher than the environmental-based preliminary remediation levels. For these sites, it may be advantageous to design a representative sampling program of the background medium to establish PQLs for use as alternative remediation goals.

9.2.3.3 Action Must Be Consistent with Other Project Phases

Understanding of the nature and extent of contamination, as well as the media and exposure pathways of concern, is a critical requirement for successful completion of the FS or CMS and remedy selection. Therefore, data used in the FS or CMS must interface with the RI/RFI and other previously collected site data. Inadequate data or data of poor quality m&present site contamination and may lead to an inadequate baseline risk assessment and FS. For each exposure pathway that presents an unacceptable ecological risk, the risk assessor and the appropriate project team members (e.g., chemist, geologist, or hydrogeologist) should review the RI data before conducting the. FS. This is particularly important when the FS is performed simultaneously with the RI, based on assumptions and PA/SI or RFA data.

RAOs may be selected based on one of the following:

- Background

Rationale: The environmental concentrations at the reference area or upgradient area will be used as RAOs since the ecological receptors or the valued resources to be protected are also located at the background locations. The reference area has the same current land use as the site and the levels are reasonable and attainable.

- RAOs are performance-based

Rationale: No reasonable chemical-specific cleanup level can be derived due to high uncertainty in the hazard-response relationship. For the purpose of remedy selection, the best available or best demonstrated remedial technology will be utilized to achieve certain risk reduction objectives according to the ECSM.

- Risk-based Remediation Go& (Cleanup GO&).

Rationale: In lieu of performance-based RAO or cleanup to the levels at the reference area risk-based RAO can be developed using dose-response information for the ecological receptor of concern or its surrogate species. The risk-based RAOs may be

adjusted upward or downward according to other risk management factors or considerations.

Minimal information or guidance has been developed by EPA regarding the development of RAOs for RCRA and Superfund sites. RCRA has issued the Alternative Concentration Limit (ACL) Guidance based on 40 CFR 264.94(b) criteria and case studies (EPA 1988j) which may be applied to developing ACLs at the source if the acceptable groundwater/surface water mixing zone concentrations and the dilution/attenuation factors are defined. Under the. proposed subpart S rule for RCRA corrective action, the state water quality criteria can be used to screen if a CMS should be conducted. For the protection of aquatic receptors, cleanup levels can be set to chemical-specific water quality criteria. Nonetheless, the key risk management issue concerning the above is that the cleanup goals must be practical and verifiable. When cleanup goals ate developed to protect both humans and ecological receptors, according to Section 300.340 of the NCP. the goals must be so adjusted that both receptor types are. protected.

Environmental and human health-based RAOs should be developed together and proposed to the risk manager and agencies for use in the CMS for the evaluation of remedial alternatives. It should be noted that the RAOs may have to be revised or refined based on other considerations, e.g., technology, matrix effects, target risks, uncertainties, and costs (associated with the extent of the remediation, management of remediation wastes, and cost of cleanup verification analyses).

Risk Management Decision

- **What are the Remedial Alternatives or Corrective Measures?**
- **What are the Preferred or Optimal Remedial Alternatives?**

Risk Management Options/Rationale

In addition to a cost and engineering evaluation of the potential remedial alternatives, each alternative must be evaluated for its ability to reduce site risk. Among the nine criteria identified by the NCP for remedy selection, protection of human health and the. environment and satisfying ARARs are considered to be the threshold (fun&-mental) criteria which must be met by any selected remedy. More recently, EPA has placed increased emphasis on short- and long-term reliability, cost, and stakeholders' acceptance in the overall goal to select remedies. Therefore, the assessment of residual risk (a measure of the extent of site risk reduction) is a critical task.

Screening and detailed analyses of remedial alternatives will be conducted in the FS and CMS project phase. The preferred remedial alternative will be proposed. As warranted, analysis of short-term risks to assess the need for control measures will be conducted in the RD project phase, and the control measure(s), if appropriate, will also be proposed.

In the FS, potential risk reductions associated with remedial alternatives am assessed. The relative success of one alternative over another is simply the ratio of the residual COEC concentrations in the exposure medium of concern. This screening evaluation does not take into account short-term risks posed by the alternative or technology due to acute hazards, releases, or spills.

9.2.3.4 Screening Evaluation of Alternatives

This evaluation focuses on determination of short-term risks posed by the removal or remedial alternatives. The findings of this evaluation are compared among the alternatives to determine preferred remedies based on the effectiveness of the remedies to satisfy remedial action goals with the least environmental impact. This screening evaluation should focus primarily on effectiveness, risk reduction, and cost.

Risk screening of alternatives should generally be qualitative or semiquantitative. If a remedy has already been selected or is highly desirable for selection, a detailed risk analysis may not be needed. Instead, the evaluation should focus on the risk reduction of the preferred remedy, and identify any concerns or data gaps which need to be addressed. The data needed to perform this screening evaluation may come from many sources: RI or RFI data, bench scale or pilot scale treatability studies conducted for the site or from comparable sites, compatibility test, test of hazardous characteristics, field monitoring measurements, vendor's or manufacturer's information, literature values, and professional judgment.'

[7] The bench sale or pilot scale treatability studies may provide valuable information for the estimation of remediation action or residual risks. Treatability studies provide data or information on the degree of removal and/or destruction of the COECs. quantity and identity of chemicals in the emissions or effluent discharges. and potential treatment standards to be applied to satisfy remedial action goals. This information is important to quantify the magnitude of risk reduction and will be useful in the comparative analysis of potential remedial alternatives.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shut-down operations).
- Toxicity of chemical substances or COECs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.
- Potential for the causation of nonchemical stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments, increased siltation and reduction of food sources for the ecological receptors of concern or other receptors/valued resources.
- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.
- Potential release of additional COECs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailabitity).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).
  - Able to remove, contain, or effectively treat site COECs.
  - Able to address the exposure pathways and media of concern.
  - Able to meet the remedial action and overall project strategy goals.
- Assessment of Residual Risk Potential.
  - Reasonable anticipated future land use (for example, if the site remains industrial/ commercial in a foreseeable future, residual risk assessment should not be performed for the potential return of and exposure to terrestrial receptors).
  - Quantity of residues or discharges to remain on site.
  - Toxicological properties of the residues.
  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities. vapor pressure, density, etc.).
  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
  - Potential for dilution and attenuation for residues released into the environment.
  - The extent of and permanence of remediation habitat destruction and alteration; for example, the construction of an access road through wetlands would be considered permanent.

9.2.3.5 Detailed Analysis of Alternatives

Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions) identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during remedial action, and residual risks if appropriate; (b) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives; and (c) identification of potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shutdown operations).
- Toxicity of chemical substances or COECs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.
- Potential for the causation of nonchemical stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments, increased siltation and reduction of food sources for the ecological receptors of concern or other receptors/valued resources.
- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.
- Potential release of additional COECs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailability).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).
  - Able to remove, contain, or effectively treat site COECs.
  - Able to address the exposure pathways and media of concern.
  - Able to meet the remedial action and overall project strategy goals.
- Assessment of Residual Risk Potential.
  - Reasonable anticipated future land use (for example, if the site remains industrial/commercial in a foreseeable future, residual risk assessment should not be performed for the potential return of and exposure to terrestrial receptors).
  - Quantity of residues or discharges to remain on site.
  - Toxicological properties of the residues.
  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities, vapor pressure, density, etc.).
  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
  - Potential for dilution and attenuation for residues released into the environment.

9.2.3.5 Detailed Analysis of Alternatives

Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions) identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during remedial action, and residual risks if appropriate: (b) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives: and (c) identification of potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

This evaluation may be qualitative. semiquantitative, or quantitative. If the analysis is quantitative, procedures and approaches similar to the baseline risk assessment may be followed. EPA's (1995g) *Air/Superfund National Technical Guidance Study Series* includes documents providing guidance for rapid assessment of exposure and risk. For example, guidance on determining the volume of soil particulates generated during excavation is provided in *Estimation of Air Impacts for the Excavation of Contaminated Soil* (EPA 19920). The data sources used to perform this risk analysis task should be similar to those identified for the screening evaluation of remedial alternatives. Although it is conceivable that the level of effort required for this analysis may be high (particularly, if the same analysis has to be performed for a number of preferred remedies), it is anticipated that the documentation and report writing will be focused and streamlined

The report should focus on the risk analysis approaches, sources of data, findings/recommendations for risk mitigation measures, and appendixes. Key factors or criteria to be considered in the screening evaluation of remedial alternatives are:

- The criteria or considerations in the assessment of short-term and residual risks are substantially similar to those identified for the screening evaluation of remedial alternatives. The key difference may be additional use of quantitative data input into the risk calculations, e.g., sediment transport modeling to evaluate the potential for migration of toxic sediment, amount of discharges or emissions, dilution/attenuation or atmospheric dispersion factors, exposure frequency, duration, and other activity patterns which could impact existing flora and fauna in time and space, and any indirect effects such as food source reduction and the extent of habitat destruction/alteration.

- Time required and extent of recovery from exposure to the above COECs and nonchemical stressors.

- The potential for fire, explosion, spill, and release of COECs from management practice of excavated or dredged materials should remain qualitative or semiquantitative. Fault-tree (engineering) analysis for accidental events may be attempted under special circumstances (e.g.. to address public comments or if demanded by citizens during public hearing of the proposed remedies).

9.2.3.6 Risks from Simultaneous Implementation of Preferred Remedies

- Common exposure pathways for effluent or discharges from remedies.

- Period of exposure to the ecological receptors of concern via the common locations, time, and pathways.

- Sensitive environments and other threatened or sensitive wildlife or aquatic populations.

- Risk estimates or characterization results.

- Toxicological evaluation for the validity of biomagnification and additivity of risk (e.g., under the Quotient Method), based on literature review, mode of action. and common target organs, etc.

- Qualitative or quantitative assessment of potential short-term or residual risks.

Short-Term Risks Associated with Construction; the Design Risk Analysis. All removal or remedial alternatives have a potential to pose short-term risks to onsite mitigation workers, ecological receptors, and offsite humans. Risks may be associated with vapors, airborne particles, treatment effluent, resuspension of sediment resulting in an increase in the total suspended solids (TSS) or siltation of substrate for macroinvertebrates, and residues generated during operation of the remedial alternative. Therefore, all the alternatives should be reviewed for their short-term risks in conjunction with data from their bench scale or pilot scale treatability studies or data from implementation of the remedy at comparable sites. The risk assessor should estimate the period of recovery from these short-term insults and determine if biological or chemical monitoring of the effects of remediation activities should be implemented. For all practical purposes, risk may remain upon completion of the remedial action (residual risk).

Long-Term Risks Associated with Alternatives: the Residual Risks. Unless all sources of contamination are removed or isolated, there will be residual risks at the site upon completion of the remedial action. The COEC residuals could either remain or be quickly degraded, depending on the COEC's physical and chemical properties. The level of residual risk will depend on the effectiveness of the remedy in containing, treating, or removing site contaminants, and the quantity, and

physical, chemical, and toxicological characteristics of residues or byproducts remaining at the site. Site COECs which remain onsite after the remedial action should be assessed for their potential risks.

This evaluation step focuses on a risk reduction assessment to determine if a potential remedial alternative is able to meet the remedial action goals and an assessment of residual risk potential. The findings of these tasks are compared among the alternatives to determine an array of preferred remedies based on the effectiveness of the remedies to satisfy remedial action goals with the least long-term health and environmental impact.

Remedial Action/Residual Risks vs. Baseline Risk. There are notable differences between remedial action/ residual risks and the baseline risk. The key difference is that baseline ecological risk refers to the potential risk to the receptors of concern under the "no remedial action" alternative. and remedial action and residual risks refer to short-term risks during remedial action and long-term risks which may remain after completion of the remedial action, respectively. Residual risk may be considered comparable to baseline ecological risk after remediation since in both cases the risks are chronic or subchronic in nature. Remedial action risks are generally short-term (acute or subchronic) risks.[8]

9.2.4 Nonrisk issues or Criteria as Determining Factors for Actions

The NCP recognizes that it is not possible to achieve zero risk in environmental cleanup: therefore, the approach taken by Superfund is to accept nonzero risk and return the site to its beat current use (not to conditions of a pre-industrialization era). Under RCRA, the preamble to the proposed Subpart S recognizes that cleanup beyond the current industrial land use should be justified. This section presents and discusses the nonrisk factors and recommends a balanced approach for resolution of issues to enable quality risk management decision-making. These factors can be categorized into scientific and nonscientific factors, as explained below.

[8] One exception (i.e., remedial action risk which is long-term) is a pump-and-treat remedy of groundwater to meet MCLs for organics which pose a threat to human health but not ecological receptors. If the effluent is discharged to a surface water body and happens to contain trace elements at high levels (or other COECs not reduced by the treatment process), then an exposure route to environment receptors may remain which is not addressed by the baseline ERA, and which will exist for the operational life span of the remedy.

9.2.4.1 Scientific Factors

The scientific factors, including engineering design and feasibility, should be considered in risk management decision-making. These factors focus on technology transfer (realistic performance of the technology), duration of protection, and feasibility study data uncertainties. These factors will influence the decision whether or not to proceed with selection of a particular remedy. They are

Technology Transfer. This factor concerns the treatability of the contaminated debris or media by a preferred technology or early action. Although the recommended technology may appear attractive, a number of problema must be overcome before actual selection or implementation of the action. The following are a few examples:

- Scale up.
- Downtime and maintenance (including supplies).
- Ownership/control.
- Throughput to meet the required completion schedule.
- Skills required or training requirements.
- Quantitation and detection limits.
- Space requirements for the remediation process and management of remediation wastes.

Duration of Protection. This factor concerns the duration of the removal or remedial technology designed to treat or address site risk. This factor is particularly important for site radionuclides or NAPL compounds in the aquifer. The maintenance or replacement of barriers or equipment is also a primary concern for this factor. Although a technology or alternative is effective, its effectiveness may not last long if there is no source control or if contamination from offsite sources is not controlled.

Data Uncertainty. This factor considers reliability and uncertainty of certain site or feasibility study data for use in selecting a remedy, or for determining whether no further action is appropriate. Uncertainty in the following data may also impact the risk analyses or baseline risk assessment results:

- Adequacy of bench-scale or pilot-scale treatability data.

- Data uncertainties (volume, matrices, site geology/hydrogeology).
- Field data and modeling data.
- Overall uncertainty of the source of site contamination.

9.2.4.2 Nonscientific Factors

Nonscientific factors should also be considered in risk management decision-making because some of these factors are key to a successful site remediation. Most of these factors are internal, but can also be external. Examples of these factors are enforcement, compliance, schedule, budget, competing risk reduction priorities, community inputs, and societal/economic value of the resources to be protected. These factors will influence the decision on whether or not certain removal or remedial actions should be taken, or on which remedies are to be selected These factors are detailed below.

Enforcement and Compliance. Certain courses of action (including risk management decisions) have been agreed upon early in the process and have been incorporated in the IAG or FFA. This is particularly germane to some earlier HTRW sites.[9] Nonetheless, the requirements specified in the enforcement documents or administrative order of consent, IAG, or FFA should be followed by the risk manager or PM with few exceptions. When risk-related factors or other nonrisk factors are over-arching, the risk manager should then raise this issue to higher echelon or to the legal department for further action or negotiation.

Competing Risk Reduction Priorities. Although related to risk, this factor represents the competing interest among programs or within the project for a limited source of funding to perform risk reduction activities. Since it is likely that not all sites will be cleaned up at an equal pace, the planning and execution of environmental restoration among these units should follow a prioritization scheme. However, the scheme developed according to risk may not be the same according to the customer, the base commander, or the agencies. The risk manager or PM must seek common ground to resolve this issue so that resources can be expended to produce incremental environmental benefits.

Schedule and Budget. These factors usually go together because the more protracted the project life, the more resources the project will demand. While each PM would like to comply with risk-based considerations with little margin of error, the PM may have no choice but to make risk management decisions with larger uncertainties than he or she would prefer, due to schedule and budget constraints.

Community Input. Opportunity for the stakeholders or community to provide input into the permit modification is provided when primary documents are prepared, i.e.. RFI Work Plan, RFI/CMS reports, the proposed remedies, and the CMI Work Plan. Superfund also provides similar opportunities for public participation. To be successful in site remediation and closeout, the risk managers must be able to communicate risks effectively in plain and clear language without bias. Early planning and solicitation of community input is essential to democratization of risk management decision-making. Some of the following issues may be of concern to the communities:

- Ineffective communication of risks and uncertainties.
- Lack of action (some action is preferred to no action).
- Not in my backyard (offsite transportation of contaminated soil, debris, or sediment should avoid residential neighborhoods).
- Any treatment effluent or discharge is unacceptable (onsite incineration is seldom a preferred option except for mobile incinerators, in certain instances).
- The remedy should not impede economic growth or diminish current economic and recreational value of resources to be protected.
- Cleanup will improve the quality of life and increase property values or restoration of recreational/ economic resources.

Societal/Economic Value of the Resources to be Protected. This nonrisk factor concerns the community sentiment on how fast or in what manner the resources

[9] USACE has published the *Technical Project Planning - - Guidance for HTRW Data Quality Design* (USACE 1995b) which purpose is to build flexibility for site decision-making based on data need, use, and project objective and strategy. This new way of project planning and execution will be likely to result in a more effective risk management decision-making for the new HTRW sites.

impacted by site contaminants should be restored. These resourcea may include surface water bodies, wildlife, and game animals. Most communities would like to see impacted resources restored to original use: however, this can be difficult to achieve. Some communities may be willing to accept natural attenuation or no action options for impacted surface water bodies, given the opportunity to examine the pros and cons of all options. Therefore, it is recommended that the risk manager execute a community relations plan in earnest in order to solicit the citizens' input on the risk reduction approach and issues of concern. Key community spokespersons may also be appointed to the site action committee to facilitate such dialogue and communication.

9.2.4.3 A Balanced Approach

In conclusion, the risk manager should consider all risk and nonrisk criteria before making risk management site decisions. Due to uncertainties associated with ERA or analysis, the decision-maker must review risk findings and the underlying uncertainties, and consider other nonrisk factors in the overall risk management equation. When making risk management decisions, the risk manager should keep an open mind regarding the approaches to meet the project objective. In order to make informed site decisions, the risk assessor must present risk estimates in an unbiased manner. With an understanding of the volume of contaminants of concern, significance and biological relevance of the ecological effects and potentially impacted receptors, fate/transport properties of the COECs, and completeness of the exposure pathways and the food web, the risk manager, PM, and stakeholders will be better equipped to make informed decisions. These decisions should be consistent with the overall site strategy, which is developed early in the project planning phase (see Chapter 2). and which may evolve throughout the project.

9.3 Design Considerations

Risk assessment methodology can be an important tool in the design phase of CERCLA remedial actions or RCRA corrective measure implementation. During the early phase of RD/RA or CMI, risk assessment results can help determine: 1) whether the selected remedy can be implemented without posing an unacceptable short-term risk or residual risk and 2) control measures (operational or engineering) to mitigate site risks and to ensure compliance with ARARs, and to-be-considered requirements, and permit conditions. The risk and safety hazard information will be evaluated by the site decision-makers, along with information concerning design criteria, performance goals, monitoring/compliance requirements, prior to making risk management decisions regarding the above questions. Further, the decision-makers consider potential requirements such as ARARs and to-be-considers TBCs) in determining design changes of control measures.

This section addresses the above issues. i.e., risk management considerations in remedial design, compliance with ARARs, including the CAA, CWA, ESA, and other major environmental statutes, and control measures required to mitigate risks.

9.3.1 Potential Risk Mitigation Measures

Engineering Control - Where appropriate (when short-term risks are determined to be unacceptable), engineering controls should be recommended by the design engineer with inputs from the risk assessor, aquatic ecologist, compliance specialist, and the air modeler. Examples of these control measures include:

- VOC and SVOC emissions - activated carbon canisters, afterburners, or flaring, prior to venting.
- Metals and SVOC airborne particles - wetting of work areas; particulate filter/bag house, wet scrubber, or electrostatic precipitator (for thermal treatment devices or incinerators).
- Fugitive emissions - monitoring of valves, pipe joints, and vessel openings: and barrier/enclosure of work areas (e.g., a can or shield over the augering stem).
- Neutralization or chemical deactivation of effluent (continuous process or batch).
- Use of remote-control vehicle for handling, opening, or cutting of drums containing explosive or highly reactive or toxic substances.

9.3.1.1 Operational Control

Where appropriate, administrative control measures (procedural and operational) safeguards should be recommended by the PM, design engineer, and field supervisor during RA, with inputs from the risk assessor and other relevant technical and compliance specialists. Examples of these control measures include:

- Establish short-term trigger levels which will require work stoppage or upgrade of the remediation procedures (e.g.. dredging of toxic sediments). Either biological or chemical indicators, or their combination could be used as the bigger levels. These levels should be developed in the RD/RA or CMI project phase by the risk assessor and other technical specialists, including the modeler.

- Consistent with the above trigger or acute concern levels. evaluate onsite performance with field equipment to ensure adequate remediation.

- Afford the proper protection of sensitive environments by careful planning and positioning of staging area. storage or management of remediation wastes, selection of equipment with low load bearing, and season or time period when the remediation should be completed.

- Establish a zone of decontamination and proper management of effluent or waste generated from this zone.

- Secure and control access to areas where remedial actions are being implemented at all times.

9.3.1.2 Institutional Control

Although institutional control may not be relevant for ecological receptors, it can be relevant in the sense that institutional control measures may be needed to reduce human intrusion, thus allowing the sensitive environments to recover or the ecological receptors to re-establish. Institutional controls are particularly pertinent for remedies which involve containment, onsite disposal of wastes, or wetlands remediation. Institutional controls should be recommended by the customer, PM, and other site decision-makers. Examples of these control measures include:

- Recording land use restrictions in the deeds (deed restrictions) for future use of certain parcels or areas where hazardous substances or wastes are contained.

- Erection of placards, labels, and markers which communicate areas where human exposure may pose short-term or residual risks.

- Security fences and barriers.

9.3.2 Risk Management; Degree of Protectiveness

Not only should a selected remedial action (corrective measure) be able to meet balancing criteria, the remedial action must be protective, i.e., in terms of reducing site risks. In designing a selected remedy, the site decision-makers may face operational or engineering issues which are likely to require risk management decisions. For example, if a detailed analysis of a selected remedy reveals potential short-term or residual risks, the decision-makers must decide to what extent and with what control measures are necessary to abate the risk. Inputs from the risk assessor will be needed to help make informed risk management decisions. The following are examples of key risk management considerations for designing an effective remediation strategy:

- **Acceptability of control measures.** There are potential operational (procedural) or engineering control measures to address the short-term risks. The risk assessor, in coordination with the design engineer, expert ecologist(s)/advisory panel, and other project team members, assesses the effectiveness of any proposed control measures.

- **Removal of control measures.** Before a control measure is implemented; the decision on the minimum performance and when to stop requiring the control measure has to be addressed. This is particularly important if control measures are costly to implement and maintain.

- **Effectiveness of the remediation.** Remediation should effectively address onsite contamination if there is a continuing offsite (regional) source. This consideration is particularly important for groundwater and sediment contamination remediation. This regional source control strategy should not be confused with the identification of PRPs since some of the discharges could be a permitted activity. Nonetheless, this issue has to be resolved if the RAOs are risk-based and do not consider offsite influences or contribution to the contaminants requiring remediation. Offsite source control and containment. waste minimization, and closure issues should be raised by the risk manager to the agencies, USACE customers, and higher echelon.

- **BRAC.** With BRAC, the land use. of closed defense facilities may not be indefinitely controlled and the legislation governing BRAC holds the U.S. government responsible for future cleanup of contamination caused by government activities. Cleanup criteria and long-term remedies should take land use into consideration for implementation of an effective site closeout strategy (see. Chapter 2). For example, conversion of military bases into a state park or refuge area will require different cleanup objectives than cleanup to the level acceptable for industrial/commercial usage. This issue should be addressed early in the site strategy development phase with input from customers, local redevelopment commissions, state, and other stakeholders.

- **Verification of cleanup.** The risk management decision concerning verification of cleanup, i.e., the numerical value of the RAO, should be based on a combination of factors: risk, uncertainty, statistics, analytical detection limits/ matrices, and costs. Although RAOs have been negotiated or determined in the ROD, the sampling method and statistical requirements must be clearly articulated before design and implementation of the corrective measures or remedial alternatives.

Risk management decisions during the design phase of a CERCLA or RCRA remediation should be flexible, considering the uncertainty in the risk assessment results, acceptable risk range, confidence level of toxicity data or criteria to support the assessment, engineering feasibility, reliability of the measures (operational changes versus pollution control equipment), state and community acceptance, and cost. It is recommended that risk managers and site decision-makers request input from all members of the project team for pros and cons of proposed control measures to address the short-term risks.

CEMP-RT Engineer Manual 200-1-5	Department of the Army U.S. Army Corps of Engineers Washington, DC 20314-1000	EM 200-1-5 1 October 1997
	Environmental Quality DESIGN, INSTALLATION AND UTILIZATION OF FIXED-FENCELINE SAMPLE COLLECTION AND MONITORING SYSTEMS	
	Distribution Restriction Statement Approved for public release; distribution is unlimited.	